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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 107

[Docket No. FAA–2024–0299]

Accepted Means of Compliance for Small Unmanned Aircraft Category 2 and Category 3 Operations Over Human Beings; Virginia Tech Mid-Atlantic Aviation Partnership (VT MAAP)

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

ACTION: Notification of availability.

SUMMARY: This document announces the acceptance of a means of compliance with FAA regulations for small unmanned aircraft (sUA) Category 2 and Category 3 operations over human beings. The Administrator finds that VT MAAP's ''Operation of Small Unmanned Aircraft Systems Over People,'' version 2.0, dated January 18, 2024, provides an acceptable means, but not the only means, of showing compliance with FAA regulations.

DATES: The means of compliance is accepted effective April 5, 2024.

FOR FURTHER INFORMATION CONTACT:

FAA Contact: Kimberly Luu, Cabin Safety Section, AIR–624, Technical Policy Branch, Policy and Standards Division, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, Washington 98198; telephone and fax 206–231–3414; email *Kimberly.H.Luu@faa.gov.*

VT MAAP Contact: Robert Briggs, UAS Chief Engineer, 1991 Kraft Drive, Suite 2018, Blacksburg, VA 24061, (540) 231–9373; *rcbriggs@vt.edu.*

SUPPLEMENTARY INFORMATION:

Background

Title 14, Code of Federal Regulations, part 107, subpart D, prescribes the eligibility and operating requirements for civil sUA to operate over human beings in the United States. To be eligible for use, the sUA must meet the requirements of § 107.120(a) for Category 2 operations or § 107.130(a) for Category 3 operations. These sections require the sUA to be designed, produced or modified such that it will not cause injury to a human being above a specified severity limit, does not contain any exposed rotating parts that would lacerate human skin, and does not contain any safety defects. Section 107.155 requires that means of compliance with § 107.120(a) or § 107.130(a) be established and FAA-accepted. Section 107.160 requires an applicant to declare that sUA for Category 2 or Category 3 operations meet an FAA-accepted means of compliance.

Means of Compliance Accepted

This notification of availability serves as a formal acceptance by the FAA of the VT MAAP's ''Operation of Small Unmanned Aircraft Systems Over People,'' version 2.0, as an acceptable means of compliance, but not the only means of compliance with §§ 107.120(a) and 107.130(a). Applicants may also propose alternative means of compliance for FAA review and possible acceptance.

Revisions

Revisions to VT MAAP's ''Operation of Small Unmanned Aircraft Systems Over People,'' version 2, will not be automatically accepted and will require further FAA acceptance for any revisions to be considered an accepted means of compliance.

Issued in Kansas City, Missouri, on April 2, 2024.

Patrick R. Mullen,

Manager, Technical Policy Branch, Policy and Standards Division, Aircraft Certification Service.

[FR Doc. 2024–07267 Filed 4–4–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 107

[Docket No. FAA–2024–0268]

Accepted Means of Compliance for Small Unmanned Aircraft Category 2 and Category 3 Operations Over Human Beings; Aerial Vehicle Safety Solutions Inc. (AVSS)

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

ACTION: Notification of availability.

SUMMARY: This document announces the acceptance of a means of compliance with FAA regulations for small unmanned aircraft (sUA) Category 2 and Category 3 operations over human beings. The Administrator finds that AVSS's means of compliance for small unmanned aircraft, revision 5.0, dated January 10, 2024, provides an acceptable means, but not the only means, of showing compliance with FAA regulations.

DATES: The means of compliance is accepted effective April 5, 2024.

FOR FURTHER INFORMATION CONTACT:

FAA Contact: Kimberly Luu, Cabin Safety Section, AIR–624, Technical Policy Branch, Policy and Standards Division, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, Washington 98198; telephone and fax 206–231–3414; email *Kimberly.H.Luu@faa.gov.*

AVSS Contact: Josh Ogden, CEO, AVSS, 570 Queen Street, Suite 600, Fredericton, New Brunswick, E3B–6Z6, Canada, +1 (650) 741–1326; *Info@avss.co.*

SUPPLEMENTARY INFORMATION:

Background

Title 14, Code of Federal Regulations, part 107, subpart D, prescribes the eligibility and operating requirements for civil sUA to operate over human beings in the United States. To be eligible for use, the sUA must meet the requirements of § 107.120(a) for Category 2 operations or § 107.130(a) for Category 3 operations. These sections require the sUA to be designed, produced, or modified such that it will not cause injury to a human being above

a specified severity limit, does not contain any exposed rotating parts that would lacerate human skin, and does not contain any safety defects. Section 107.155 requires that means of compliance with § 107.120(a) or § 107.130(a) be established and FAA-accepted. Section 107.160 requires an applicant to declare that sUA for Category 2 or Category 3 operations meet an FAA-accepted means of compliance.

Means of Compliance Accepted

This notification of availability serves as a formal acceptance by the FAA of the AVSS's ''Means of Compliance with §§ 107.120(a) and 107.130(a) for Small Unmanned Aircraft,'' revision 5.0, as an acceptable means of compliance, but not the only means of compliance with §§ 107.120(a) and 107.130(a). Applicants may also propose alternative means of compliance for FAA review and possible acceptance.

Revisions

Revisions to AVSS's ''Means of Compliance (MOC) with §§ 107.120(a) and 107.130(a) for Small Unmanned Aircraft (sUA),'' revision 5.0, will not be automatically accepted, and will require further FAA acceptance for any revisions to be considered an accepted means of compliance.

Issued in Kansas City, Missouri, on April 2, 2024.

Patrick R. Mullen,

Manager, Technical Policy Branch, Policy and Standards Division, Aircraft Certification Service.

[FR Doc. 2024–07266 Filed 4–4–24; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 723, 724, 845, and 846

RIN 1029–AC86

[Docket ID: OSM 2024–0001; S1D1S SS08011000 SX064A000 245S180110; S2D2SSS08011000 SX064A00 24XS501520]

Civil Monetary Penalty Inflation Adjustments

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule.

SUMMARY: Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Act), which further amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (1990 Act), and Office of Management and Budget guidance, this rule adjusts for inflation the level of civil monetary penalties assessed under the Surface Mining Control and Reclamation Act of 1977 (SMCRA) and its implementing regulations.

DATES: Effective April 5, 2024.

FOR FURTHER INFORMATION CONTACT: Khalia A. Boyd, Office of Surface Mining Reclamation and Enforcement, 1849 C Street NW, Mail Stop 4558, Washington, DC 20240; Telephone (202) 208–2823. Email: *kboyd@osmre.gov*.

SUPPLEMENTARY INFORMATION:

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I. Background

A. The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015

Section 518 of SMCRA, 30 U.S.C. 1268, authorizes the Secretary of the Interior to assess civil monetary penalties (CMPs) for violations of SMCRA. The Federal regulations implementing the CMP provisions of section 518 are located in 30 CFR parts 723, 724, 845, and 846. The Office of Surface Mining Reclamation and Enforcement (OSMRE) is adjusting CMPs in six sections: 30 CFR 723.14, 723.15, 724.14, 845.14, 845.15, and 846.14.

On November 2, 2015, the President signed the 2015 Act into law (Sec. 701 of Pub. L. 114–74). The 2015 Act, which amended the 1990 Act (Pub. L. 101–410), requires Federal agencies to promulgate rules to adjust the level of CMPs to account for inflation. The 2015 Act requires agencies to publish annual inflation adjustments. These adjustments are aimed at maintaining the deterrent effect of civil penalties and furthering the policy goals of the statutes that authorize the penalties.

B. Calculation of Adjustments

The Office of Management and Budget (OMB) issued guidance on the 2024 annual adjustments for inflation. December 19, 2023, Memorandum for the Heads of Executive Departments and Agencies (M–24–07), *Implementation of Penalty Inflation Adjustments for 2024, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015* (OMB Memorandum). The OMB Memorandum notes that the 1990 Act defines ''civil monetary penalty'' as ''any penalty, fine, or other sanction that . . . is for a specific monetary amount as provided by Federal law; or . . . has a maximum amount provided for by Federal law; and . . . is assessed or enforced by an agency pursuant to Federal law; and . . . is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts . . . .'' *Id.* at 2. It further instructs that agencies ''are to adjust 'the maximum civil monetary penalty or the range of minimum and maximum civil monetary penalties, as applicable, for each civil monetary penalty by the cost-of-living adjustment.' '' *Id.* The 1990 Act, as amended by the 2015 Act, and the OMB Memorandum specify that the annual inflation adjustments are based on the percent change between the Consumer Price Index for all Urban Consumers (the CPI–U) published by the Department of Labor for the month of October in the year of the previous adjustment, and the October CPI–U for the preceding year. The recent OMB Memorandum specified that the cost-of-living adjustment multiplier for 2024, not seasonally adjusted, is 1.03241 (the October 2023 CPI–U (307.671) divided by the October 2022 CPI–U (298.012) = 1.03241). OSMRE used this guidance to identify applicable CMPs and calculate the required inflation adjustments. The 1990 Act, as amended by the 2015 Act, specifies that any resulting increases in CMPs must be rounded according to a stated rounding formula and that the increased CMPs apply only to CMP assessments that occur after the date that the increases take effect.

Generally, OSMRE assigns points to a violation as described in 30 CFR 723.13 and 845.13. The CMP owed is based on the number of points received, ranging

from one point to 70 points. For example, under our existing regulations in 30 CFR 845.14, a violation totaling 70 points would amount to a $19,815 CMP. To adjust this amount, OSMRE multiplied $19,815 by the 2023 inflation factor of 1.03241, resulting in a raw adjusted amount of $20,457.20. Because the 2015 Act requires rounding any increase in the CMP amount to the nearest dollar, in this case a violation of 70 points would amount to a new CMP of $20,457. Pursuant to the 2015 Act, the increases in this Final Rule apply to CMPs assessed after the date the increases take effect, even if the associated violation predates the applicable increase.

There are no points associated with 30 CFR 723.15(b), 30 CFR 724.14(b), 30 CFR 845.15(b), and 30 CFR 846.14(b) because those regulatory provisions do not set forth numbers of points, only dollar amounts.

C. Effect of the Rule in Federal Program States and on Indian Lands

OSMRE directly regulates surface coal mining and reclamation operations within a State or on Indian lands if the State or Tribe does not obtain its own approved program pursuant to sections 503 or 710(j) of SMCRA, 30 U.S.C. 1253 or 1300(j). The increases in CMPs contained in this rule will apply to the following Federal program States: Arizona, California, Georgia, Idaho, Massachusetts, Michigan, North Carolina, Oregon, Rhode Island, South Dakota, Tennessee, and Washington. The Federal programs for those States appear at 30 CFR parts 903, 905, 910, 912, 921, 922, 933, 937, 939, 941, 942, and 947, respectively. Under 30 CFR 750.18, the increases in CMPs also apply to Indian lands under the Federal program for Indian lands.

D. Effect of the Rule on Approved State Programs

As a result of litigation, State regulatory programs are not required to mirror all of the penalty provisions of our regulations. *See In re Permanent Surface Mining Regul. Litig.,* No. 79–1144, 1980 U.S. Dist. LEXIS 17722, at *21–23 (D.D.C. Feb. 26, 1980); 1980 U.S. Dist. LEXIS 17660, at *87–88 (D.D.C. May 16, 1980). Thus, this rule has no effect on CMPs in States with SMCRA primacy.

II. Procedural Matters

A. Regulatory Planning and Review (Executive Orders 12866, 13563, and 14094)

Executive Order (E.O.) 14094 reaffirms the principles of E.O. 12866 and E.O. 13563 and states that regulatory analysis should facilitate agency efforts to develop regulations that serve the public interest, advance statutory objectives, and are consistent with E.O. 12866, E.O. 13563, and the Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review). E.O. 12866, as reaffirmed by E.O. 13563 and E.O. 14094, provides that the Office of Information and Regulatory Affairs (OIRA) within OMB will review all significant rules. OIRA has determined that agency regulations exclusively implementing the annual inflation adjustments and that are consistent with the OMB Memorandum, such as this rule, are not significant.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires an agency to prepare a regulatory flexibility analysis for all rules unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which an agency is required to first publish a proposed rule. *See* 5 U.S.C. 603(a) and 604(a). The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 requires agencies to adjust civil penalties annually for inflation ''notwithstanding section 553 [of the Administrative Procedure Act].'' Thus, no proposed rule will be published, and the RFA does not apply to this rulemaking.

C. Congressional Review Act

This rule is not a major rule under 5 U.S.C. 804(2), the Congressional Review Act. This rule:

(a) Will not have an annual effect on the economy of $100 million or more.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

(c) Will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises.

D. Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or Tribal governments, or the private sector, of more than $100 million per year. The rule does not have a significant or unique effect on State, local, or Tribal governments, or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

E. Takings (Executive Order 12630)

This rule does not effect a taking of private property or otherwise have takings implications under E.O. 12630. A takings implication assessment is not required.

F. Federalism (Executive Order 13132)

Under the criteria in section 1 of E.O. 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. A federalism summary impact statement is not required.

G. Civil Justice Reform (Executive Order 12988)

This rule complies with the requirements of E.O. 12988. Specifically, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

H. Consultation With Indian Tribes (Executive Order 13175 and Departmental Policy)

The Department of the Interior strives to strengthen its government-to-government relationship with Tribes through a commitment to consultation with Tribes and recognition of their right to self-governance and Tribal sovereignty. OSMRE has evaluated this rule under the Department's consultation policy, under Departmental Manual Part 512, Chapters 4, 5, 6, and 7 and under the criteria in E.O. 13175 and has determined that it has no substantial direct effects on Federally-recognized Tribes or Alaska Native Claims Settlement Act (ANCSA) Corporations, and that consultation under the Department's Tribal and ANCSA consultation policies is not required.

I. Paperwork Reduction Act

This rule does not contain information collection requirements, and a submission to OMB under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) is not required. OSMRE may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number.

J. National Environmental Policy Act

This rule does not constitute a major Federal action under the National Environmental Policy Act of 1969 (NEPA) because of the non-discretionary nature of the civil penalty adjustment as required by law (*see* 40 CFR 1508.1(q)(1)(ii)). The 2015 Act requires OSMRE to annually adjust the amounts of its civil penalties to account for inflation as measured by the Department of Labor's Consumer Price Index. Accordingly, OSMRE has no discretion in the execution of the civil penalty adjustments reflected in this final rule. Because this rule is not a major Federal action, it is therefore not subject to the requirements of NEPA. Even if this were a discretionary action subject to NEPA, which it is not, a detailed statement under NEPA would nevertheless not be required because, as a regulation of an administrative nature, this rule would otherwise be covered by a categorical exclusion (*see* 43 CFR 46.210(i)). OSMRE has determined that the rule does not implicate any of the extraordinary circumstances listed in 43 CFR 46.215 that would prevent reliance on the categorical exclusion. Therefore, a detailed statement under NEPA is not required.

K. Effects on Energy Supply, Distribution, and Use (Executive Order 13211)

This rule is not a significant energy action under the definition in E.O. 13211. A Statement of Energy Effects is not required.

L. Administrative Procedure Act

OSMRE is issuing this final rule without prior public notice or opportunity for public comment. The 2015 Act requires agencies to publish adjusted penalties annually. Under the 2015 Act, the public procedure that the Administrative Procedure Act generally requires—notice, an opportunity for comment, and a delay in the effective date—is not required for agencies to issue regulations implementing the annual adjustments required by the 2015 Act. *See* OMB Memorandum, M–24–07, at 3–4.

M. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 3701 *et seq.*) directs Federal agencies to use voluntary consensus standards when implementing regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. This final rule is not subject to the requirements of section 12(d) of the NTTAA because application of those requirements would be inconsistent with SMCRA, and the requirements would not be applicable to this final rulemaking.

N. Protection of Children From Environmental Health Risks and Safety Risks (Executive Order 13045)

E.O. 13045 requires that environmental and related rules separately evaluate the potential impact to children. However, E.O. 13045 is inapplicable to this rulemaking because this is not a substantive rulemaking, and a notice of proposed rulemaking was neither required nor prepared. *See* sections 2–202 and 5–501 of E.O. 13045.

List of Subjects

30 CFR Part 723

Administrative practice and procedure, Penalties, Surface mining, Underground mining.

30 CFR Part 724

Administrative practice and procedure, Penalties, Surface mining, Underground mining.

30 CFR Part 845

Administrative practice and procedure, Law enforcement, Penalties, Reporting and recordkeeping requirements, Surface mining, Underground mining.

30 CFR Part 846

Administrative practice and procedure, Penalties, Surface mining, Underground mining.

Delegation of Signing Authority

The action taken herein is pursuant to an existing delegation of authority.

Steven H. Feldgus,

Principal Deputy Assistant Secretary, Land and Minerals Management.

For the reasons given in the preamble, the Department of the Interior amends 30 CFR parts 723, 724, 845, and 846 as set forth below.

PART 723—CIVIL PENALTIES

■ 1. The authority citation for Part 723 continues to read as follows:

Authority: 28 U.S.C. 2461, 30 U.S.C. 1201 *et seq.,* and 31 U.S.C. 3701.

■ 2. Amend § 723.14 by revising table 1 to read as follows:

§ 723.14 Determination of amount of penalty.

* * * * *

TABLE 1 TO § 723.14

Points	Dollars
1	82
2	164
3	246
4	327
5	410
6	491
7	573
8	651
9	736
10	819
11	899
12	982
13	1,061
14	1,145
15	1,230
16	1,309
17	1,391
18	1,475
19	1,555
20	1,636
21	1,720
22	1,801
23	1,882
24	1,963
25	2,045
26	2,455
27	2,864
28	3,271
29	3,527
30	4,091
31	4,499
32	4,910
33	5,319
34	5,729
35	6,137
36	6,547
37	6,956
38	7,365
39	7,773
40	8,182
41	8,594
42	9,002
43	9,408
44	9,819
45	10,228
46	10,638
47	11,046
48	11,457
49	11,864
50	12,273
51	12,681
52	13,093
53	13,502
54	13,912
55	14,322
56	14,730
57	15,137
58	15,546
59	15,957
60	16,365
61	16,774
62	17,183
63	17,593
64	18,002
65	18,410
66	18,821
67	19,230
68	19,637
69	20,047
70	20,457

■ 3. Amend § 723.15 by revising paragraph (b) introductory text to read as follows:

§ 723.15 Assessment of separate violations for each day.

* * * * *

(b) In addition to the civil penalty provided for in paragraph (a) of this section, whenever a violation contained in a notice of violation or cessation order has not been abated within the abatement period set in the notice or order or as subsequently extended pursuant to section 521(a) of the Act, 30 U.S.C. 1271(a), a civil penalty of not less than $3,068 will be assessed for each day during which such failure to abate continues, except that:

* * * * *

PART 724—INDIVIDUAL CIVIL PENALTIES

■ 4. The authority citation for Part 724 continues to read as follows:

Authority: 28 U.S.C. 2461, 30 U.S.C. 1201 *et seq.,* and 31 U.S.C. 3701.

■ 5. In § 724.14, revise the first sentence of paragraph (b) to read as follows:

§ 724.14 Amount of individual civil penalty.

* * * * *

(b) The penalty will not exceed $20,457 for each violation. * * *

PART 845—CIVIL PENALTIES

■ 6. The authority citation for Part 845 continues to read as follows:

Authority: 28 U.S.C. 2461, 30 U.S.C. 1201 *et seq.,* 31 U.S.C. 3701, Pub. L. 100–202, and Pub. L. 100–446.

■ 7. Amend § 845.14 by revising table 1 to read as follows:

§ 845.14 Determination of amount of penalty.

* * * * *

TABLE 1 TO § 854.14

Points	Dollars
1	82
2	164
3	246
4	327
5	410
6	491
7	573
8	651
9	736
10	819
11	899
12	982
13	1,061
14	1,145
15	1,230
16	1,309
17	1,391
18	1,475
19	1,555
20	1,636
21	1,720
22	1,801
23	1,882
24	1,963
25	2,045
26	2,455
27	2,864
28	3,271
29	3,527
30	4,091
31	4,499
32	4,910
33	5,319
34	5,729
35	6,137
36	6,547
37	6,956
38	7,365
39	7,773
40	8,182
41	8,594
42	9,002
43	9,408
44	9,819
45	10,228
46	10,638
47	11,046
48	11,457
49	11,864
50	12,273
51	12,681
52	13,093
53	13,502
54	13,912
55	14,322
56	14,730
57	15,137
58	15,546
59	15,957
60	16,365
61	16,774
62	17,183
63	17,593
64	18,002
65	18,410
66	18,821
67	19,230
68	19,637
69	20,047
70	20,457

■ 8. Amend § 845.15 by revising paragraph (b) introductory text to read as follows:

§ 845.15 Assessment of separate violations for each day.

* * * * *

(b) In addition to the civil penalty provided for in paragraph (a) of this section, whenever a violation contained in a notice of violation or cessation order has not been abated within the abatement period set in the notice or order or as subsequently extended pursuant to section 521(a) of the Act, 30 U.S.C. 1271(a), a civil penalty of not less than $3,068 will be assessed for each day during which such failure to abate continues, except that:

* * * * *

PART 846—INDIVIDUAL CIVIL PENALTIES

■ 9. The authority citation for Part 846 continues to read as follows:

Authority: 28 U.S.C. 2461, 30 U.S.C. 1201 *et seq.,* and 31 U.S.C. 3701.

■ 10. In § 846.14, revise the first sentence of paragraph (b) to read as follows:

§ 846.14 Amount of individual civil penalty.

* * * * *

(b) The penalty will not exceed $20,457 for each violation. * * *

[FR Doc. 2024–07205 Filed 4–4–24; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0269]

RIN 1625–AA00

Safety Zone; Heavy Weather and Natural or Other Disasters in San Juan Captain of the Port Zone, Sector San Juan

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a safety zone to be enforced in the event of hurricanes, tropical storms, and other disasters in the San Juan Captain of the Port (COTP) Zone. This action is necessary to ensure the safety of the waters of the San Juan COTP zone. This regulation establishes actions to be completed by parties operating on and around the navigable waterways of the San Juan COTP zone. This may include the owners and operators, and those in management and control positions of regulated facilities, waterfront facilities, and vessels, prior to landfall of hurricanes, tropical storms, and other disasters threatening the San Juan COTP Zone.

DATES: This rule is effective May 6, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2023–0269 in the search box and click ''Search.'' Next, in the Document Type

column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Lieutenant Commander (LCDR) Carlos M. Ortega-Pérez, the Waterways Management Division Chief, Sector San Juan Prevention Department, U.S. Coast Guard; telephone 787–729–2380, email *Carlos.M.Ortega-Perez@uscg.mil*.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

COTP Captain of the Port
CFR Code of Federal Regulations
CWA Clean Water Act
DHS Department of Homeland Security
FR Federal Register
MTSA Maritime Transportation Security Act
NPRM Notice of proposed rulemaking
OPA90 The Oil Pollution Act of 1990
PWSA Ports and Waterways Safety Act
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

During the hurricane season Puerto Rico and the Virgin Islands face different security and life-threatening challenges that directly affect the safety and continuity of operations of the Sector's waterways and port facilities. To ensure the safety of the port and life on navigable waters of the United States this regulation restricts movement of vessels and barges over 500 gross tons (GT) in the event of heavy weather conditions or any natural or other disasters anticipated to affect the San Juan Captain of the Port (COTP) zone. The COTP has determined that reduced or restricted visibility and gale force winds which may occur during heavy weather periods and other disasters affecting Puerto Rico and the U.S. Virgin Islands, constitutes a safety concern for the navigable waters and waterfront facilities within the San Juan COTP zone.

In response, on June 13, 2023, the Coast Guard published a notice of proposed rulemaking (NPRM) titled, ''Safety Zone: Heavy Weather and Natural or Other Disasters in San Juan Captain of the Port Zone, San Juan, PR.'' [1] There we stated why we issued the NPRM and invited comments on our proposed regulatory action related to this heavy weather or other disasters. During the comment period that ended June 29, 2023, we received no comments.

While there were no comments, a similar NPRM was published for the Key West COTP zone which garnered two public comments.[2] The Coast Guard made changes to the regulatory text in the final rule for the Key West COTP zone [3] for clarity in response to the comments received. In this final rule, the Coast Guard made similar changes in the regulatory text for consistency with the Key West COTP zone. See 33 CFR 165.707.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The purpose of this rule is to protect the general maritime public, to include vessel owners, vessel operators, and those in management and control positions related to facilities and waterways regulated by the Coast Guard, along with those in management and control positions related to any land or shore area immediately adjacent to those waterways in the San Juan COTP zone, in the event of a hurricane, tropical storm, and other natural disasters.

IV. Discussion of Comments, Changes, and the Rule

As a general matter, this rule is intended to inform the general maritime public, to include vessel owners and operators, regulated facilities, and waterfront facilities of the Coast Guard's expectations in the event of a hurricane, tropical storm, or other disaster, thereby expediting the enforcement of the safety zone, and providing more advanced notice of the Coast Guard's expectations in the event of a hurricane, tropical storm, or other natural disaster. This rule is also intended to provide vessel owners and operators, along with the owners and operators of regulated facilities and waterfront facilities with a deeper understanding of how the Coast Guard intends to handle extreme weather-related events so they can plan accordingly.

As noted in the previous section, we received no comments on our NPRM published June 13, 2023. However, due to the thorough review done during the similar NPRM published for the Sector Key West COTP zone, we have determined that there are several changes in the final rule's regulatory text for 33 CFR 165.791 as follows.

To clarify some potential confusion, the Coast Guard is adding two definitions for ''regulated facilities,'' and ''waterfront facilities,'' in paragraph(a). The Coast Guard has the authority to regulate facilities and land structure or shore area immediately adjacent to navigable waters under certain, specific statutory and regulatory frameworks. We are adding a definition for ''regulated facilities'' to clarify the regulated facilities covered by this rule are those regulated under the Ports and Waterways Safety Act,[4] Maritime Transportation and Security Act (MTSA),[5] Clean Water Act,[6] and the Oil Pollution Act of 1990.[7] These statutes give the Coast Guard the authority and jurisdiction to take certain actions on certain regulated facilities that have a maritime nexus. We are adding a definition for ''waterfront facilities'' which will include any land structure or shore area immediately adjacent to the navigable waters of the San Juan COTP zone.

When the safety zone is subject to enforcement it will be determinate of conditions set forth in paragraphs (c)(1) through (c)(5). In paragraphs (c)(1), we are deleting ''port facilities'' and adding in its place, ''regulated facilities and waterfront facilities'' for consistency as definitions for these terms have been added in paragraphs (b)(6) and (b)(7). In the event Port Condition WHISKEY is set, all vessels, regulated facilities, and waterfront facilities within the San Juan COTP zone would have to comply with the applicable regulations in paragraph (c)(1). Additionally, in paragraph (c)(1), we removed the sentence, ''Vessels wishing to remain in port are required to submit an application to the COTP prior to setting Port Condition X-Ray.'' In its place, we are adding the sentence, ''Oceangoing vessels greater than 500 gross tons (GT) intending to remain in the port during Port Condition Whiskey must contact the San Juan COTP prior to the setting of port condition X-Ray.'' We are taking this action to prevent vessel owners and operators from having to generate additional documentation.

In paragraphs (c)(2), we are deleting ''port facilities'' and adding in its place, ''regulated facilities and waterfront facilities'' for consistency as definitions for these terms have been added in paragraphs (a)(7) and (a)(8). In the event Port Condition X–RAY is set, all vessels, regulated facilities, and waterfront facilities within the San Juan COTP zone would have to comply with the applicable regulations in paragraph (c)(2). Additionally, in paragraph (c)(2), we are deleting the sentence, ''The COTP may require additional precautions to ensure the safety of the ports and waterways'' because it is

[1] 88 FR 38413.

[2] 88 FR 27421.

[3] See Final rule titled, ''Safety Zone; Atlantic Ocean, Key West, FL'' (88 FR 76133).

[4] 46 U.S.C. 70001 *et seq.*

[5] 46 U.S.C. 70101 *et seq.*

[6] 33 U.S.C. 1251 *et seq.*

[7] 33 U.S.C. 2701 *et seq.*

overly vague and may cause undue confusion for owners and operators of vessels and regulated facilities.

In paragraph (c)(3), we clarified we are only limiting cargo operations at ''regulated facilities.'' We also removed some the language that went into specifics of cargo operations. Removing the language made the regulatory text more succinct, as the initial language contained unnecessary redundancies. We also clarified that only facilities regulated under the MTSA will be required to operate in accordance with their security plan.

In paragraph (c)(4), we are removing the words ''are suspended'' and replacing it with, ''must cease all cargo operations'' because the phrase ''are suspended'' may be confusing in this context. By using the phrase ''must cease all cargo operations'' we are making it clear to the regulated parties that cargo operations must stop when Port ZULU is set.

In paragraph (c)(7), we are revising the text to clarify that the Coast Guard Sector San Juan will notify the maritime community, ''to the furthest extent practicable'' of the periods which the safety zone in paragraph (a) will be subject to enforcement via Broadcast Notice to Mariners or by on-scene designated representatives.

Lastly, we are making non-substantive editorial changes and revising terminology for consistency throughout the final rule regulatory text.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the following reasons: (1) Vessel traffic and facilities will be impacted by this rule only during limited times while heavy weather or other disaster is expected to impact the Sector San Juan COTP zone; (2) vessel traffic would be secured only during port conditions Yankee and Zulu, and only in port areas potentially affected by gale force winds; and (3) the Coast Guard would issue updates on *https://homeport.uscg.mil/port-directory/san-juan,* Broadcast Notice to Mariners, and during Port Coordination meetings.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969(42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone of limited duration implemented during heavy weather events *e.g.,* tropical storms, hurricanes, or other natural disasters where a safety zone implementation is deemed appropriate by the COTP. It is categorically

excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.791 to read as follows:

§ 165.791 Safety Zones; Heavy Weather and Natural or Other Disasters in San Juan Captain of the Port Zone.

(a) *Location.* The following area is a safety zone: All navigable waters, as defined in 33 CFR 2.36, within Sector San Juan Captain of the Port (COTP) zone, San Juan, Puerto Rico, as described in 33 CFR 3.35–25, during specified conditions.

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

(1) *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 COTP San Juan in the enforcement of the safety zone.

(2) *Gale force winds* means sustained surface winds, or frequent gusts, of 34 knots (39 mph) or more usually seen in coastal regions.

(3) *Port Condition WHISKEY* means a condition set by the COTP when gale force winds are expected to make landfall at the port within 72 hours.

(4) *Port Condition X–RAY* means a condition set by the COTP when gale force winds are expected to make landfall at the port within 48 hours.

(5) *Port Condition YANKEE* means a condition set by the COTP when gale force winds are expected to make landfall at the port within 24 hours.

(6) *Port Condition ZULU* means a condition set by the COTP when gale force winds are expected to make landfall at the port within 12 hours.

(7) *Regulated facilities* means shoreside facilities regulated by the Coast Guard under the Ports and Waterways Safety Act,[8] Maritime Transportation and Security Act,[9] Clean Water Act,[10] and the Oil Pollution Act of 1990,[11] and regulations in 33 CFR parts 105, 154, 156, and 158.

(8) *Waterfront facilities* means any land structure or shore area immediately adjacent to the navigable waters of the San Juan COTP zone.

(c) *Regulations.* (1) *Port Condition WHISKEY.* All vessels, regulated facilities, and waterfront facilities within the San Juan COTP zone must exercise due diligence in preparation for potential storm impacts. All regulated facilities and waterfront facilities must begin removing all debris and securing potential flying hazards. Oceangoing vessels greater than 500 gross tons (GT) must make plans to depart no later than the setting of Port Condition Yankee unless authorized by the COTP. Oceangoing vessels greater than 500 GT intending to remain in port must contact the COTP prior to the setting port condition X-Ray.

(2) *Port Condition X–RAY.* All vessels, regulated facilities, and waterfront facilities within the San Juan COTP zone must ensure that potential flying debris is removed or secured. Hazardous materials/pollution hazards must be secured in a safe manner and away from waterfront areas. Vessels greater than 500 GT without an approval to remain in port must depart prior to the setting of Port Condition YANKEE. Vessels with the COTP's permission to remain in port must implement their pre-approved mooring arrangement. Regulated facilities must prepare to terminate all cargo operations.

(3) *Port Condition YANKEE.* Affected ports are closed to inbound vessel traffic. All oceangoing vessels greater than 500 GT must have departed designated ports within the San Juan COTP zone. Regulated facilities must terminate all cargo operations, not associated with storm preparations, unless specifically authorized by the COTP. All MTSA regulated facilities must continue to operate in accordance with their approved Facility Security Plans and comply with the requirements of the MTSA.

(4) *Port Condition ZULU.* The port is closed to all vessel traffic except as specifically authorized by the COTP. Regulated facilities must cease all cargo operations, including bunkering and lightering. Waivers may be granted except for when Cargo of Particular Hazard or Certain Dangerous Cargo are involved.

(5) *Emergency Regulation for Other Disasters.* Any natural or other disasters that are anticipated to affect the Sector San Juan COTP zone will result in the prohibition of facility operations and vessel traffic transiting or remaining in the affected port.

(6) *Transit requests.* Persons and vessels desiring to enter, transit through, anchor in, or remain in the regulated area may contact the COTP via telephone at (787) 289–2041, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, anchor in, or remain in the regulated area is granted by the COTP or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the COTP or a designated representative.

(7) *Safety zones notice.* Coast Guard Sector San Juan will notify the maritime community, to the furthest extent practicable, of the periods during which the safety zone described in paragraph (a) will be subject to enforcement via Broadcast Notice to Mariners or by on-scene designated representatives.

Dated: April 1, 2024.

Robert M. Pirone,

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

[FR Doc. 2024–07228 Filed 4–4–24; 8:45 am]

BILLING CODE 9110–04–P

[8] 46 U.S.C. 70001 *et seq.*

[9] 46 U.S.C. 70101 *et seq.*

[10] 33 U.S.C. 1251 *et seq.*

[11] 33 U.S.C. 2701 *et seq.*

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0228]

RIN 1625–AA87

Security Zone; Cooper River, Charleston, SC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone for navigable waters of the Cooper River, in the vicinity of the Arthur Ravenel Jr. Bridge, in Mount Pleasant, SC. This security zone is necessary to provide for the security and protection of life of participants and spectators during the Cooper River Bridge Run event. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Charleston or a designated representative.

DATES: This rule is effective from 7:30 a.m. through 10:30 a.m., on April 6, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2024–0228 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Marine Science Technician First Class Thomas J. Welker, Sector Charleston, Waterways Management Division, U.S. Coast Guard; telephone 843–740–3184, email *Thomas.J.Welker@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. The Coast Guard did not receive the information required to develop and finalize plans for an official patrol of the security zone in ample time to allow for public comment for the Cooper River Bridge Run event scheduled on April 6, 2024. The Coast Guard lacks sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule. It would be impracticable to delay promulgating this rule, as it is necessary to protect the safety of participants and spectators participating in this event, and to mitigate potential subversive acts.

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

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70051 and 70124. The Captain of the Port (COTP) Charleston has determined that the presence of persons under the protection of the Coast Guard in the Sector Charleston COTP zone presents a potential target for terrorist attack, sabotage, or other subversive acts, accidents, or other causes of similar nature. The rule is needed to protect persons under the protection of the Coast Guard, personnel in and around the Cooper River Bridge Run event.

IV. Discussion of the Rule

This rule establishes a security zone in Mount Pleasant, SC, from 7:30 a.m. through 10:30 a.m. on April 6, 2024. The security zone would cover all navigable waters of the Cooper River, in the vicinity of the Arthur Ravenel Jr. Bridge.

Entry into this security zone is prohibited unless specifically authorized by the Captain of the Port (COTP) or their designated representative. A designated representative is a commissioned, warrant, or petty officer of the Coast Guard assigned to units under the operational control of the Coast Guard Sector Charleston. Requests for entry will be considered and reviewed on a case-by-case basis. The COTP may be contacted by telephone at 843–740–3184 or can be reached by VHF–FM channel 16. Persons and vessels permitted to enter these security zones must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or their designated representative.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, duration, and time-of-year of the security zone. This security zone will impact a small, designated area on the navigable waters of Cooper River for approximately three hours during a time of year when vessel traffic is normally low. To alleviate the effects of this rule on the public, the COTP may elect to temporary suspend enforcement of this security zone. Moreover, the Coast Guard will issue Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

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

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

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

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's

responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a security zone lasting only 3 hours that will prohibit entry into all navigable waters of the Cooper River, in the vicinity of the Arthur Ravenel Jr. Bridge. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T07–0228 to read as follows:

§ 165.T07–0228 Security Zone; Cooper River Bridge Run, Charleston, SC.

(a) *Location.* The following area is a security zone: All waters of the Cooper River, and Town Creek Reaches encompassed within the following points: Beginning at 32°48′32″ N, 079°56′08″ W, thence east to 32°48′20″ N, 079°54′18″ W, thence south to 32°47′20″ N, 079°54′29″ W, thence west to 32°47′20″ N, 079°55′28″ W, thence north to origin. All coordinates are 1984 World Geodetic System (WGS 84).

(b) *Regulations.* (1) Under the general security zone regulations in subpart D of this part, you may not enter the security zone described in paragraph (a) of this section unless authorized by the Captain of the Port Sector Charleston (COTP) or the COTP's designated representative.

(2) Vessels requiring entry into the security zone must request permission from the COTP or a designated representative. To seek entry into the security zone, contact the COTP or the COTP's representative by telephone at 843–740–7050 or on VHF–FM channel 16.

(3) Persons and vessels permitted to enter the security zone must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative.

(c) *Definitions.* As used in this section, *designated representative* is a commissioned, warrant, or petty officer of the Coast Guard assigned to units under the operational control of Coast Guard Sector Charleston.

(d) *Enforcement period.* This section will be enforced from 7:30 a.m. through 10:30 a.m. on April 6, 2024.

Dated: April 1, 2024.

F.J. DelRosso,

Captain, U.S. Coast Guard, Captain of the Port Sector Charleston.

[FR Doc. 2024–07235 Filed 4–4–24; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2022–0955; FRL–10549–02–R9]

Approval of Implementation Plans for Air Quality Planning Purposes; State of Nevada; Clark County Second 10-Year Maintenance Plan for the 1997 8-Hour Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve, as a revision of the Nevada state implementation plan (SIP), the State's second 10-year plan for maintaining the 1997 8-hour ozone standard in Clark County (''Clark County Second Maintenance Plan'' or ''Plan''). The Clark County Second Maintenance Plan includes, among other elements, a base year emissions inventory, a maintenance demonstration, contingency provisions, and motor vehicle emissions budgets for use in transportation conformity determinations to ensure the continued maintenance of the 1997 National Ambient Air Quality Standards for ozone (''1997 ozone NAAQS'' or ''1997 8-hour ozone standard''). With this action, the EPA is approving the motor

vehicle emissions budgets for 2017, 2023, and 2033. The EPA is taking this final action because the SIP revision meets the applicable statutory and regulatory requirements for such plans and motor vehicle emissions budgets.

DATES: This action is effective on May 6, 2024.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2022–0955. 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 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: Andrew Ledezma, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 972–3985 or by email at *Ledezma.Andrew@epa.gov.*

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

Table of Contents

I. Summary of Proposed Action

On December 21, 2023, the EPA proposed to approve two submittals from the Nevada Division of Environmental Protection (NDEP) as a revision to the Nevada SIP: the Clark County Second Maintenance Plan dated December 21, 2021, and a supplement to the Clark County Second Maintenance Plan (''Contingency Provision Supplement'') dated August 16, 2023.[1] We refer to the Clark County Second Maintenance Plan and the Contingency Provision Supplement collectively as the ''Clark County Second Maintenance Plan.'' We proposed to find that the Clark County Second Maintenance Plan adequately demonstrates that the Clark County area will maintain the 1997 ozone NAAQS through 2033 (*i.e.,* for more than 10 years beyond the first 10-year maintenance period), with the maintenance period ending on February 7, 2033. We also proposed to find that the Plan includes sufficient contingency provisions to promptly correct any violation of the 1997 ozone NAAQS that may occur. Lastly, we proposed to find that the motor vehicle emissions budgets (''budgets'') for volatile organic compounds (VOC) and nitrogen oxides (NO_X) for 2017, 2023, and 2033 were adequate.

Please see our proposed rule for a detailed discussion of the background for this action and substantive review of the Clark County Second Maintenance Plan and associated budgets.

II. Public Comments and EPA Responses

Our December 21, 2023 proposed rule provided a 30-day public comment period that closed on January 22, 2024. During this comment period we received no comments on our proposal.

III. Final Action

Under CAA section 110(k)(3), and for reasons set forth in our December 21, 2023 proposed rule, the EPA is taking final action to approve the Clark County Second Maintenance submittal as a revision to the Nevada SIP. The EPA finds that the maintenance demonstration showing the area will continue to maintain the 1997 ozone NAAQS for an additional 10 years beyond the first maintenance period, and the contingency provisions describing the actions that NDEP will take in the event of a future monitored violation, meet all applicable requirements for maintenance plans and related contingency provisions in CAA section 175A. The EPA is also approving the budgets for VOC and NO_X for 2017, 2023, and 2033 because they are derived from an approvable maintenance demonstration and are adequate and meet the applicable transportation conformity requirements under 40 CFR 93.118(e).

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this 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 action:

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

In addition, there are no areas of Indian country within the planning area, and the state plan for which the EPA is approving does 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 Clark County Second Maintenance Plan does not apply, and therefore, this action does not have tribal implications and would not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 12898 (Federal Actions To Address Environmental

[1] 88 FR 88300.

Justice in Minority Populations and Low-Income Populations, 59 FR 7629, Feb. 16, 1994) directs Federal agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. The EPA defines environmental justice (EJ) as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' The EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.''

The air agency did not evaluate EJ considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. The EPA's evaluation of environmental justice is described in the proposed rule titled, ''Environmental Justice Considerations.'' The analysis was done for the purpose of providing additional context and information about this rulemaking to the public, not as a basis of the action. Due to the nature of the action being taken here, this action is expected to have a neutral to positive impact on the air quality of the affected area. In addition, there is no information in the record upon which this decision is based that is inconsistent with the stated goal of E.O. 12898 of achieving environmental justice for people of color, low-income populations, and Indigenous peoples.

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 June 4, 2024. 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 dioxide, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: March 29, 2024.

Martha Guzman Aceves,

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 DD—Nevada

■ 2. In § 52.1470 in paragraph (e), amend the table by adding an entry for ''Revision to Motor Vehicle Emissions Budgets in Ozone Redesignation Request and Maintenance Plan: Clark County, Nevada (October 2018)'' after the entry for ''Ozone Redesignation Request and Maintenance Plan, Clark County, Nevada (March 2011)'' to read as follows:

§ 52.1470 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED NEVADA NONREGULATORY AND QUASI-REGULATORY MEASURES

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanation
Air Quality Implementation Plan for the State of Nevada [1]				
* *	* *	*	*	*
Second Maintenance Plan for the 1997 8-hour Ozone NAAQS, Clark County, Nevada (December 2021), and Revision to Contingency Measures Plan in the Second Maintenance Plan for the 1997 8-hour Ozone NAAQS (July 2023).	Las Vegas, Nevada: that portion of Clark County that lies in hydrogeographic areas 164A, 164B, 165, 166, 167, 212, 213, 214, 216, 217, and 218, but excluding the Moapa River Indian Reservation and the Fort Mohave Indian Reservation.	Clark County Second Maintenance Plan: 1/24/2022, Contingency Measure Revision: 8/16/2023.	[INSERT **FEDERAL REGISTER** CITATION], 4/5/2024.	Fulfills requirement for second ten-year maintenance plan.
* *	* *	*	*	*

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

[FR Doc. 2024–07199 Filed 4–4–24; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–HQ–ES–2023–0018; FXES1113090FEDR–245–FF09E23000]

RIN 1018–BF88

Endangered and Threatened Wildlife and Plants; Regulations Pertaining to Endangered and Threatened Wildlife and Plants

AGENCY: U.S. Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), revise our regulations concerning protections of endangered species and threatened species under the Endangered Species Act (Act or ESA). We reinstate the general application of the ''blanket rule'' option for protecting newly listed threatened species pursuant to section 4(d) of the Act, with the continued option to promulgate species-specific section 4(d) rules. We also extend to federally recognized Tribes the exceptions to prohibitions for threatened species that the regulations currently provide to the employees or agents of the Service and other Federal and State agencies to aid, salvage, or dispose of threatened species. We also make minor changes to clarify or correct the existing regulations for endangered species and threatened species; these minor changes do not alter the substance or scope of the regulations.

DATES: This final rule is effective May 6, 2024.

ADDRESSES: Public comments and materials received, as well as supporting documentation used in the preparation of this final rule, are available at *https://www.regulations.gov* at Docket No. FWS–HQ–ES–2023–0018.

FOR FURTHER INFORMATION CONTACT: Carey Galst, Branch of Listing and Policy Support, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, Falls Church, VA 22041–3803; telephone 703/358–1954. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Background

The purposes of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.* (the Act)), are to provide a means to conserve the ecosystems upon which listed species depend, develop a program for the conservation of listed species, and achieve the purposes of certain treaties and conventions. Moreover, it is the policy of Congress that the Federal Government will seek to conserve endangered species and threatened species and use its authorities to further the purposes of the Act (16 U.S.C. 1531(c)(1)). This rulemaking action pertains primarily to sections 4 and 9 of the Act.

Section 9 of the Act provides a specific list of prohibitions for endangered species but does not provide these same prohibitions to threatened species. Instead, the first sentence in section 4(d) of the Act requires that the Secretary issue regulations that are necessary and advisable to provide for the conservation of threatened species; these are referred to as ''4(d) rules.'' In addition, the second sentence of section 4(d) authorizes the Secretary to prohibit with respect to any threatened species any act prohibited under section 9 with respect to endangered species. With these two sentences in section 4(d), Congress delegated the authority to the Secretary to determine what protections would be necessary and advisable to provide for the conservation of threatened species, and even broader authority to put in place any of the section 9 prohibitions, for a given species. Early in the administration of the Act, the Service promulgated ''blanket rules,'' two sets of protective regulations that generally applied to threatened species of wildlife and plants, at 50 CFR 17.31 and 17.71, respectively. These regulations extended the majority of the protections (all of the prohibitions that apply to endangered species under section 9 with certain exceptions to those prohibitions) to threatened species, unless we issued an alternative rule under section 4(d) of the Act for a particular species (*i.e.,* a species-specific 4(d) rule). For species with a species-specific 4(d) rule, that rule contains all of the protective regulations for that species.

On August 27, 2019, we issued a final rule that revised 50 CFR 17.31 and 17.71 (84 FR 44753; hereinafter, ''the 2019 4(d) rule'') and ended the ''blanket rule'' option for application of section 9 prohibitions to species newly listed as threatened after the effective date of those regulatory revisions (September 26, 2019). The ''blanket rule'' protections continued to apply to threatened species that were listed prior to September 26, 2019, without an associated species-specific 4(d) rule. Under the 2019 4(d) rule, the only way to apply protections to a species newly listed as a threatened species is for us to issue a species-specific 4(d) rule setting out the protective regulations that are appropriate for that species.

On January 20, 2021, the President issued Executive Order 13990 (86 FR 7037, January 25, 2021; hereinafter referred to as ''the E.O.''), which required all agencies to review agency actions issued between January 20, 2017, and January 20, 2021, to determine consistency with the purposes articulated in section 1 of the E.O. Pursuant to the direction in the E.O., we reviewed our 2019 4(d) rule to assess whether to keep it in place or to revise any aspects. Our review included evaluating the benefits or drawbacks of the regulations as revised in the 2019 4(d) rule, the necessity of those regulations, their consistency with applicable case law, and other factors. Based on our evaluation, and for reasons discussed in more detail below, we revise our regulations at 50 CFR 17.31 and 17.71 to reinstate the ''blanket rules'' that apply the section 9 prohibitions to newly listed threatened species, and we also update other provisions in 50 CFR part 17. The updated prohibitions and exceptions differ from the previous ''blanket rules'' in two substantive ways. First, federally recognized Tribes are now included as entities authorized to aid, salvage, or dispose of threatened species without a permit. Second, as a result of updating our endangered plant regulations at 50 CFR 17.61(c)(1) to match amendments to the Act that Congress enacted in 1988, threatened plants protected under the previous ''blanket rule'' are now protected from being maliciously damaged or destroyed on areas under Federal jurisdiction, or being removed, cut, dug up, or damaged or destroyed on any other area in knowing violation of any law or regulation of any State or in the course of any violation of a State criminal trespass law. With these regulation revisions, we are not required to reevaluate any previously finalized species-specific 4(d) rules. However, any threatened species with a species-specific 4(d) rule that refers to 50 CFR 17.31(b) or 17.71(b) now has the updated prohibitions and exceptions. In

addition, any threatened species of wildlife or plant protected with the previous ''blanket rules'' has the updated prohibitions and exceptions as outlined under 50 CFR 17.31(a) or 17.71(a), respectively, for any future actions after the effective date of this rule (see **DATES**, above).

The Secretaries of the Interior and Commerce share responsibilities for implementing most of the provisions of the Act. Generally, marine species and some anadromous (sea-run) species are under the jurisdiction of the Secretary of Commerce, and all other species are under the jurisdiction of the Secretary of the Interior. Authority to administer the Act has been delegated by the Secretary of the Interior to the Director of the U.S. Fish and Wildlife Service (''the Service'') and by the Secretary of Commerce to the Assistant Administrator for the National Marine Fisheries Service (NMFS). The Service and NMFS (jointly ''the Services'') each have separate regulations for implementation of section 4(d) protective regulations for species within their respective jurisdictions. As was the case when we amended our section 4(d) regulations in 2019, the amendments in this rule affect only species under Service jurisdiction.

The 2019 4(d) rule, along with other revisions to the Act's regulations finalized in 2019 (revisions to 50 CFR parts 402 and 424), were subject to litigation in the United States District Court for the Northern District of California. On July 5, 2022, the court issued a decision vacating the 2019 4(d) rule without reaching the merits of the case. On September 21, 2022, the United States Court of Appeals for the Ninth Circuit temporarily stayed the effect of the July 5th decision pending the District Court's resolution of motions seeking to alter or amend that decision. On October 14, 2022, the Services notified the District Court that we anticipated proceeding with a rulemaking process to revise the 2019 4(d) rule. Subsequently, on November 16, 2022, the District Court issued orders granting the Service's motion to remand the 2019 4(d) rule to the Service without vacating it. On June 22, 2023, we published in the **Federal Register** (88 FR 40742) a proposed rule to amend the regulations to reinstate the ''blanket rule'' for newly listed threatened species, to extend certain exceptions to federally recognized Tribes, and to make minor clarifications and corrections. We accepted public comments on the June 22, 2023, proposed rule for 60 days, ending August 21, 2023. With this rule, the Service is finalizing these amendments to our regulations at 50 CFR part 17.

This rule is one of three rules publishing in this issue of the **Federal Register** that change regulations that implement the Act. Two of these rules are joint between the Service and NMFS, and this document is specific to the Service.

This Rulemaking Action

We are revising the regulations in 50 CFR part 17, subparts C, D, F, and G, with minor administrative revisions to subpart A. We reinstate the general application of the ''blanket rule'' option for protecting newly listed threatened species pursuant to section 4(d) of the Act, with the continued option to craft species-specific 4(d) rules (50 CFR 17.31(a) and 17.71(a)). We add federally recognized Tribes to the entities authorized to aid or salvage threatened species (50 CFR 17.31(b) and 17.71(b)(1)). We also update endangered plant regulatory protections to mirror existing protections at section 9(a)(2)(B) of the Act (50 CFR 17.61(c)(1)) and clarify that State conservation agencies have the authority to ''take'' threatened species when carrying out conservation programs unless a species-specific 4(d) rule specifically prohibits that take (50 CFR 17.31(c) and 17.71(c)). Finally, we make minor changes to clarify, without changing the scope or intent of, the existing regulations in several locations (*e.g.,* 50 CFR 17.21, 17.31, 17.32), as well as technical corrections such as revising the use of the phrase ''special rule'' to ''species-specific rule'' in several locations (*e.g.,* 50 CFR 17.8, 17.40). In the event any provision is invalidated or held to be impermissible as a result of a legal challenge, the ''remainder of the regulation could function sensibly without the stricken provision.'' *Belmont Mun. Light Dep't* v. *FERC,* 38 F.4th 173, 187 (D.C. Cir. 2022) (quoting *MD/DC/DE Broad. Ass'n* v. *FCC,* 236 F.3d 13, 22 (D.C. Cir. 2001)). Because each of the provisions stands on its own, the Service views each of the provisions as operating independently from the other provisions. To illustrate this with one possible example, in the event that a reviewing Court were to find that the provision extending to Tribes the authority to aid threatened species without a permit is invalid, that finding would not affect the revisions to our endangered plant regulations which incorporate the 1988 amendments to the Act. Therefore, in the event that any portion of this final rule is held to be invalid or impermissible, the Service intends that the remaining aspects of the regulatory provisions be severable.

Reinstatement of Blanket Rules

The primary revisions are to 50 CFR 17.31 and 17.71; the revisions reinstate the general application of the ''blanket rule'' options for protecting newly listed threatened wildlife and plant species, respectively, pursuant to section 4(d) of the Act. ''Blanket rule'' protections are but one option for protecting threatened species; thus, we also retain the option to promulgate species-specific 4(d) rules.

Our regulations describing the protections included in either ''blanket rule'' are found at 50 CFR 17.31(a) and 17.71(a) for wildlife and plants, respectively. They include protections from our endangered species regulations at 50 CFR 17.21 and 17.61, thereby incorporating all of the section 9 prohibitions, which make it illegal for any person subject to the jurisdiction of the United States to engage in the following actions:

- With respect to endangered fish or wildlife—take such a species within the United States or on the high seas; or possess, sell, deliver, carry, transport, or ship any such species that has been taken illegally;
- With respect to endangered plants—remove and reduce to possession, or maliciously damage or destroy, any such plants from areas under Federal jurisdiction; or remove, cut, dig up, or damage or destroy such plants on any other area in knowing violation of any State law or regulation or in the course of violating any State criminal trespass law; and
- With respect to endangered fish or wildlife or plants—import or export any such species; deliver, receive, carry, transport, or ship any such species in interstate or foreign commerce in the course of commercial activity; or sell or offer for sale in interstate or foreign commerce any such species (16 U.S.C. 1538(a)(1) and (a)(2); 50 CFR 17.21 and 17.61).

Our endangered species regulations also include a suite of exceptions, which allow for various entities to conduct otherwise prohibited acts without a permit under the Act (*e.g.,* any person may take endangered wildlife in defense of their own life or the lives of others; Federal and State law enforcement officers may possess, deliver, carry, transport, or ship any endangered wildlife taken in violation of the Act as necessary in performing their official duties; certain individuals can take wildlife to aid, salvage, or dispose of endangered species).

Protections for threatened species under the ''blanket rules'' also include these standard exceptions; however,

because threatened species are not in danger of extinction but are likely to become so within the foreseeable future, we provide additional flexibility for managing threatened species. At 50 CFR 17.31(b) and 17.71(b), we include for threatened species exceptions that are more numerous or broader than those for endangered species. These include additional exceptions for the Service and NMFS to conduct otherwise prohibited acts without a permit under the Act associated with carrying out conservation actions and broader exceptions for agents or employees of State conservation agencies operating a conservation program in accordance with section 6(c) of the Act to conduct otherwise prohibited acts without a permit under the Act. These specific exceptions were available in ''blanket rules'' prior to the 2019 4(d) rule, and we are reinstating them. We also extend to federally recognized Tribes the exceptions to prohibitions for threatened species that the regulations currently provide to the employees or agents of the Services and other Federal and State agencies to aid, salvage, or dispose of threatened species (see the preamble of our June 22, 2023, proposed rule (88 FR 40742 at 40745–40746) for further discussion of our rationale, which has not changed in this final rule). We have found these base protections and exceptions make sense for most threatened species (see *Necessary and Advisable Determination,* below).

While we can put these base protections into species-specific 4(d) rules and craft species-specific 4(d) rules for every threatened species, we find reinstating the ''blanket rule'' option to be a superior choice. This is because whenever we determine that the standard suite of protections and exceptions is appropriate, we will not need to develop any additional regulatory text to codify a species-specific 4(d) rule. It is more straightforward and transparent to have species-specific 4(d) rules in one place in the Code of Federal Regulations and ''blanket rule'' protections described in another, as we had done for the 40 years prior to September 26, 2019. This approach will result in less confusion, less duplication of regulatory text in the Code of Federal Regulations, a lower risk of error in transposing regulatory text, and reduced administrative costs associated with developing and publishing a rule in the **Federal Register** and Code of Federal Regulations.

Reinstating the ''blanket rule'' option also ensures there is never a lapse in threatened species protections. If we do not promulgate a species-specific 4(d) rule at the time of listing, the ''blanket rule'' protections will be in place to provide for the conservation of that threatened species. We are simply providing a streamlined option for protecting threatened species for situations in which we do not promulgate species-specific 4(d) rules.

Our ability to tailor ''take'' prohibitions or other protections to what is necessary and advisable for a given species is an important tool to further the conservation of threatened species and will not be affected by reinstating the ''blanket rule'' option. Prior to our 2019 4(d) rule, we also had the option to issue species-specific 4(d) rules, which we did approximately 25 percent of the time. Species-specific 4(d) rules can: (1) facilitate implementation of beneficial conservation actions and (2) reduce or otherwise tailor permitting requirements for prohibited actions (*e.g.,* take) under circumstances that are considered inconsequential to the conservation of the species, which can also make better use of our limited personnel and fiscal resources and reduce regulatory burden.

For every newly listed threatened species, we will determine what section 4(d) protections are appropriate. We anticipate that for some species we will determine that a species-specific 4(d) rule would be appropriate while for other species we will determine that ''blanket rule'' protections are appropriate. When we find that the suite of protections (prohibitions and exceptions) at § 17.31(a) or § 17.71(a) is appropriate for a given species, we will state it in the preamble of the proposed and final rule listing a species as a threatened species, and we will not develop any additional regulatory text that would appear as a species-specific 4(d) rule (at 50 CFR 17.40 through 17.48 (for wildlife) or 17.73 through 17.78 (for plants)). When we determine that species-specific 4(d) rules are appropriate, we intend to finalize those species-specific 4(d) rules concurrently with final listing rules. In most cases, we will propose the species-specific 4(d) rule concurrently with the proposed listing rule. Whether proposing to protect a threatened species with a ''blanket rule'' or a species-specific 4(d) rule, the public will be afforded an opportunity to provide public comment on the proposed action.

Effects to Currently Listed Threatened Species

Reinstating the ''blanket rule'' option and other regulation revisions will only result in minor changes to protections for currently listed threatened species, whether those species received 4(d) protections from the prior versions of the ''blanket rules'' or from a species-specific 4(d) rule. Species that were protected under prior versions of the ''blanket rules'' or under species-specific 4(d) rules that refer to any of the sections we are revising receive the updated protections for any actions occurring after the effective date of this rule (see **DATES**, above). As stated above, the revised prohibitions and exceptions make only two substantive changes to the protections for those previously listed threatened species. First, we add federally recognized Tribes to the entities authorized to aid, salvage, or dispose of threatened species. Second, as a result of updating our endangered plant regulations at 50 CFR 17.61(c)(1) to match amendments to the Act that Congress enacted in 1988, threatened plants protected under the previous ''blanket rule'' are now protected from being maliciously damaged or destroyed on areas under Federal jurisdiction, or being removed, cut, dug up, or damaged or destroyed on any other area in knowing violation of any law or regulation of any State or in the course of any violation of a State criminal trespass law.

All of the relevant changes associated with this rulemaking will similarly change any existing species-specific 4(d) rules for experimental populations that include references to 50 CFR 17.21 or 17.31 (there are no current experimental populations for plants).

Corrections and Clarifications

In addition to the revisions above, we are also revising multiple sections of 50 CFR part 17, including sections related to protections for endangered plants, to improve readability, increase consistency among sections, align with the Act, and correct inaccuracies. Here we provide additional information on our update to our endangered plant regulations. See our June 22, 2023, proposed rule (88 FR 40742 at 40745–40746) for additional details about the remaining changes.

We are updating our endangered plant regulations at 50 CFR 17.61(c)(1) to match amendments to the Act that Congress enacted in 1988 (16 U.S.C. 1538(a)(2)(B); ESA section 9(a)(2)(B); Pub. L. 100–478 (October 7, 1988)). The House Report at the time concluded that the amendments were necessary because, without them, ''anyone [could] pick, dig up, cut or destroy an endangered plant with impunity'' unless the action was committed on an area under Federal jurisdiction and the plant removed from that area (H. Rept. No. 100–467 (December 7, 1987)). To

ensure that our regulations conform to the statutory language regarding prohibitions for endangered plants, we are adding a provision that also makes it unlawful to: (a) maliciously damage or destroy an endangered plant species on an area under Federal jurisdiction; or (b) remove, cut, dig up, or damage or destroy an endangered plant species on any area that is not under Federal jurisdiction in knowing violation of a State law or regulation or in the course of violating a State criminal trespass law. This regulatory revision does not alter existing protections for endangered plant species, as they already had these protections through the Act itself. This revision is a simple correction to our regulations to match the statutory language at section 9(a)(2)(B). As stated above, our ''blanket rule'' for threatened plant species incorporates the protections from our endangered plant regulations; therefore, threatened plants protected by the plant ''blanket rule'' receive this additional protection.

Necessary and Advisable Determination

As further discussed below, we are not required to make a ''necessary and advisable'' determination when we apply or do not apply specific section 9 prohibitions to a threatened species (*In re: Polar Bear Endangered Species Act Listing and 4(d) Rule Litigation,* 818 F. Supp. 2d 214, 228 (D.D.C. 2011) (citing *Sweet Home Chapter of Cmtys. for a Great Or.* v. *Babbitt,* 1 F.3d 1, 8 (D.C. Cir. 1993), *rev'd on other grounds,* 515 U.S. 687 (1995))). Nevertheless, even though we are not required to make such a determination, we have chosen to be as transparent as possible and explain below why applying our regulatory text at 50 CFR 17.31(a) and 17.71(a) is, as a whole, necessary and advisable to provide for the conservation of threatened species unless a species-specific 4(d) rule is developed.

Section 4(d) provides two separate authorities. First, the Secretary ''shall'' issue whatever regulations they deem necessary and advisable to provide for the conservation of any threatened species. Second, the Secretary ''may'' choose to prohibit for a threatened species any of the activities that section 9 prohibits for endangered species.

The first sentence of section 4(d) in the Act has two components: a requirement (to issue regulations for threatened species, if there are any that meet the standard) and a standard (that the regulations be necessary and advisable to provide for the conservation of the species). Thus, we must determine what regulations, if any, are necessary and advisable to provide for the conservation of the species, and if so, promulgate them. We interpret the statutory language (''necessary and advisable to provide for the conservation of the species'') to focus the standard for 4(d) rules on providing for the conservation of the species. Therefore, within that context we have interpreted the ''necessary and advisable'' language to establish a single standard, and we do not attempt to evaluate or make independent findings as to whether a 4(d) rule is separately ''necessary'' and ''advisable.'' This interpretation was upheld by the court in *In re: Polar Bear Endangered Species Act Listing and 4(d) Rule Litigation,* 818 F. Supp. 2d 214, 234 (D.D.C. 2011) (referring to ''Congress's broad delegation of authority to the Secretary to determine what measures are necessary and advisable to provide for the conservation of threatened species''). For species that we list as threatened in the future and protect using the ''blanket rules'' found at 50 CFR 17.31(a) and 17.71(a), we will not make separate ''necessary and advisable'' determinations for the use of those ''blanket rules.'' Rather, we explain here why use of the ''blanket rules'' is generally necessary and advisable to provide for the conservation of threatened species unless we issue a species-specific 4(d) rule for a given species. (For species-specific 4(d) rules, we will continue to include the rationale for why the rule as a whole is necessary and advisable to provide for the conservation of the species that is the subject of the rule, as has been our past practice.)

The Act defines an ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range, and a ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act provides a specific list of prohibitions for endangered species under section 9, but the Act does not provide these same prohibitions to threatened species. Therefore, when we conduct a rulemaking action to list a species as a threatened species, we recognize that the species is likely to become at risk of extinction within the foreseeable future, and we will either promulgate a species-specific 4(d) rule to establish regulations to provide for the conservation of the species or the species will be afforded protections under the ''blanket rules'' at § 17.31(a) or § 17.71(a), as was the case for species listed prior to September 26, 2019.

The second source of authority in section 4(d) states that the Secretary may by regulation prohibit with respect to any threatened species any act prohibited under section 9(a)(1), in the case of fish or wildlife, or section 9(a)(2), in the case of plants. The use of the word ''may,'' along with the absence of any specific standards, in the second sentence grants us particularly broad discretion to put in place for threatened species any of the prohibitions that section 9 contains for endangered wildlife and plants. These prohibitions make it illegal for any person subject to the jurisdiction of the United States to engage in the following actions:

- With respect to endangered fish or wildlife—take such a species within the United States or on the high seas; or possess, sell, deliver, carry, transport, or ship any such species that has been taken illegally;
- With respect to endangered plants—remove and reduce to possession, or maliciously damage or destroy, any such plants from areas under Federal jurisdiction; or remove, cut, dig up, or damage or destroy such plants on any other area in knowing violation of any State law or regulation or in the course of violating any State criminal trespass law; and
- With respect to endangered fish or wildlife or plants—import or export any such species; deliver, receive, carry, transport, or ship any such species in interstate or foreign commerce in the course of commercial activity; or sell or offer for sale in interstate or foreign commerce any such species (16 U.S.C. 1538(a)(1) and (a)(2); 50 CFR 17.21 and 17.61).

The statute does not require us to make a finding that our decision to apply, or not to apply, specific section 9 prohibitions to a threatened species is necessary and advisable to provide for the conservation of the species. However, it is most transparent if in this rule we describe our rationale for why the regulatory texts that we are finalizing at §§ 17.31(a) and 17.71(a) (''blanket rules'') are, as a whole, necessary and advisable to provide for the conservation of threatened species.

For every listed threatened species, we will determine what section 4(d) protections are appropriate. We anticipate that for some species we will determine that species-specific 4(d) protections would be appropriate while for other species we will determine that ''blanket rule'' protections are appropriate. In circumstances in which we find that ''blanket rule'' protections are appropriate, we will reference this final rule as our explanation for why a ''blanket rule'' is necessary and advisable for the species. In contrast, in circumstances in which we determine

species-specific 4(d) protections are appropriate, we will explain in the preamble to the rule why the species-specific 4(d) rule, as a whole, satisfies the requirement in section 4(d) of the Act to issue regulations deemed necessary and advisable to provide for the conservation of that species. Further, when we develop species-specific 4(d) rules, we are not ''removing'' or ''adding'' protections compared to the ''blanket rules''; therefore, for newly listed threatened species, we will not compare or contrast the protections at § 17.31(a) or § 17.71(a) with any of the individual proposed species-specific protective regulations. We will simply discuss why the species-specific rule, as a whole, is necessary and advisable for that species.

We conclude for two primary reasons that applying section 9 prohibitions and exceptions to those prohibitions similar to our longstanding ''blanket rules'' that were available prior to the 2019 4(d) rule is necessary and advisable for the conservation of a threatened species unless we promulgate species-specific 4(d) protections for that species.

The first reason is biological: We want to prevent declines in the species' status, and section 4(d) provides that the Secretary shall promulgate regulations that are necessary and advisable to provide for the conservation of the species. Although threatened species are not currently in danger of extinction like endangered species, we have determined those species are likely to become in danger of extinction within the foreseeable future, and we have an opportunity to try to prevent that from happening. In furtherance of the conservation purposes of the Act identified in section 2(b) (16 U.S.C. 1531(b)), Congress put in place the section 9 prohibitions as an immediate way after listing endangered species to help prevent further declines in the species' status. The plain language of section 4(d) indicates that the Secretary may by regulation prohibit acts under section 9, and we have concluded that applying those prohibitions in the ''blanket rules'' upon the listing of threatened species will similarly help prevent further declines of the species and further the conservation purposes of the Act.

Another aspect of our biological reason to apply section 9 prohibitions similar to our longstanding ''blanket rules'' is that, for newly listed species, we often lack a complete understanding of the causes of a species' decline, and taking a precautionary approach to applying protections would proactively address potentially unknown threats. In addition, the initial listing of a species may bring new attention to the species, and that attention may increase the risk of collection or sale. Therefore, this approach of applying section 9 prohibitions to threatened species under the ''blanket rules'' assists our goal of putting in place protections that will both prevent the species from becoming endangered and promote the recovery of species. As we learn more about a given species and the reasons for its decline over time, we have the option to establish or revise species-specific 4(d) rules accordingly.

As discussed above, the ''blanket rules'' also include standard exceptions to the section 9 prohibitions. Providing these exceptions to threatened species afforded protections under a ''blanket rule'' helps to conserve the species by incentivizing conservation through reducing unneeded permitting (*e.g.,* to allow take associated with aiding injured wildlife).

The second reason for applying the section 9 prohibitions for endangered species to threatened species under a ''blanket rule'' is a practical reason. The first sentence of section 4(d) is open-ended—requiring only that we issue protective regulations that are ''necessary and advisable to provide for the conservation of the species.'' But in most situations, for purposes of implementation and enforcement, it is easier to explain and comprehend protections for threatened species if they are modeled after the section 9 prohibitions for endangered species—with which agency staff and the public are widely familiar. Therefore, rather than craft similar, but slightly different, prohibitions for threatened species, we refer directly to endangered species regulations at 50 CFR 17.21 and 17.61, where appropriate, in our ''blanket rules'' as well as in most species-specific 4(d) rules.

For all these reasons, we have determined, even though we are not required to do so, that the ''blanket rules'' are necessary and advisable to provide for the conservation of threatened species except for those species for which we issue species-specific 4(d) rules.

Relationship to Section 10(j)

Pursuant to section 10(j) of the Act, members of experimental populations are generally treated as threatened species, and pursuant to 50 CFR 17.81, experimental populations are designated through population-specific regulations found in §§ 17.84 through 17.86. Under our existing practice, each population-specific regulation contains all of the applicable prohibitions, along with any exceptions to prohibitions, for that experimental population. Further, our regulations at 50 CFR 17.81(f) state that any population of an endangered species or a threatened species determined by the Secretary to be an experimental population in accordance with subpart H of part 17 will be identified by a species-specific 4(d) rule in §§ 17.84 and 17.85 as appropriate and separately listed in § 17.11(h) (wildlife) or § 17.12(h) (plants) as appropriate. Per those regulations, all experimental populations will have a species-specific 4(d) rule.

Additional Considered Provision

While not proposed as regulatory text, in the proposed rule we solicited comments on an additional potential exception in 50 CFR 17.31(b) and 17.71(b) that would extend an exception to the prohibitions to certain individuals from federally recognized Tribes for take associated with conservation-related activities. After review of public comments received (see Summary of Comments and Responses, below), we are not revising the regulations to include this particular exception at this time. We are finalizing the regulations as proposed to allow federally recognized Tribes to aid or salvage threatened species without a permit.

Summary of Comments and Responses

In our June 22, 2023, proposed rule (88 FR 40742), we requested public comments by August 21, 2023. We received more than 150,000 comments by that date. We received comments from a range of sources, including individual members of the public, States, Tribes, industry organizations, legal foundations and firms, and environmental organizations. We received several requests for extensions of the public comment period. However, we elected not to extend the public comment period beyond the original 60-day public comment period because we found the 60-day comment period provided sufficient time for a thorough review of the proposed revisions. The majority of the proposed revisions are to portions of the regulations that were previously revised in 2019, and we publicly announced in a press release and on a Service website our intention to revise these regulations in June of 2021. The number of comments received indicated that members of the public were aware of the proposed rule and had adequate time to review it. In addition, we provided six informational sessions for a wide variety of audiences. Over 500 attendees participated in these sessions, and we addressed questions from the participants as part of the

sessions. Finally, on our website, we provided additional information about the regulations, such as frequently asked questions and a prerecorded presentation on the proposed revisions.

Most of the comments we received were nonsubstantive in nature, expressing either general support for, or opposition to, provisions of the proposed rule with no supporting information or analysis. Other comments expressed opinions regarding topics not covered within the proposed regulation. For example, we received comments focused on issues that may arise during implementation of our regulations such as opinions as to the scope of the Service's discretion in extending section 9 prohibitions in future species-specific 4(d) rules. We note that, for each future application of a ''blanket rule'' or promulgation of a species-specific 4(d) rule, the Service will provide an opportunity for public comment. The vast majority of the comments received were nearly identical statements from individuals indicating their general support for the proposed changes to the regulations but not containing substantive content. We also received approximately 90 letters with detailed substantive comments with specific rationales for support of or opposition to specific portions of the proposed rule. Below, we summarize and respond to the significant, substantive comments we received by the close of the comment period.

Reinstatement of Blanket Rules

Comment 1: Multiple commenters supported reinstatement of the ''blanket rules.'' Many agreed that we may not fully understand the threats to a species or threats may change after listing a species. They noted that, when appropriate, future species-specific 4(d) rules can be promulgated outside the time constraints required by the listing process, and after species and land-management needs are fully understood to further the conservation of the threatened species. Others suggested reinstating the ''blanket rule'' options allows the Service to best uphold the purposes of the Act while streamlining its implementation and maximizing efficiency.

Response: We appreciate the comments and include similar reasons for reinstating the ''blanket rules'' in our rationale in the preamble of this document.

Comment 2: Multiple commenters addressed the question of whether ''blanket rules'' are legal under the Act, including whether they are consistent with congressional intent. Some commenters suggested that the rules are not legal because the statutory language and legislative history indicate that Congress intended for the protections for threatened species to differ from, and be more flexible than, the protections for endangered species, as well as for the Service to develop a separate and individualized set of protective regulations for each threatened species. On the other hand, other commenters viewed the ''blanket rules'' as legal and consistent with congressional intent. These commenters pointed out that ''blanket rules'' further the purposes of the Act by allowing the Service to protect species quickly without having to develop a new set of regulations for each species, and that courts have upheld the ''blanket rules'' that were in place before the Service promulgated the 2019 4(d) rule.

Response: We considered all of the comments and have reached the conclusion that promulgating ''blanket rules'' is legal under the Act and consistent with the intent of Congress. Section 4(d) of the Act requires that, whenever a species is listed as a threatened species, the Service must issue protective regulations that are necessary and advisable to provide for the conservation of the species, but there is nothing in the statute that prevents us from first issuing ''blanket rules'' proactively that we can later decide whether to apply to species that we list as a threatened species or to promulgate a species-specific 4(d) rule for that species. Nor do the specific words that commenters quote from section 4(d) of the statute (such as ''*any* threatened species'' and ''*any* act prohibited under section [9]'') and from the legislative history (such as ''*that* species'' and ''*particular* threatened species,'' S. Rpt. No. 93–307, at 8 (June 30, 1973)) require that regulations extending the section 9 prohibitions apply only to individual species. ''Species'' is both the single and the plural form of the word, so ''any species'' could refer to any ''one or more species.'' In addition, there are specific words in the legislative history that point towards multiple species (for example, a statement about threatened species in the context of section 4(d) that there is ''almost an infinite number of options available to [the Secretary] with regard to permitted activities for *those species*'' in H.R. Rep. No. 93–412, at 12 (1973)). The court in *Sweet Home Chapter of Communities for a Greater Oregon* v. *Babbitt* ruled that this approach is consistent with the ESA (1 F.3d. 1, 8 (D.C. Cir. 1993), *modified on other grounds on reh'g,* 17 F.3d 1463 (D.C. Cir. 1994), *rev'd on other grounds,* 515 U.S. 687 (1995)).

With respect to comments stating that in the statute Congress took differing approaches between the prohibitions in section 9 that apply automatically to endangered species upon listing and the more flexible provisions in section 4(d), we are retaining flexibility with the ''blanket rules'' because we still determine for each threatened species whether to adopt species-specific 4(d) protections or to retain the ''blanket rule'' protections. Reinstating the ''blanket rules'' does not itself prohibit any acts with respect to any future-listed threatened species; rather, the moment at which that occurs is when we list that species as a threatened species and decide either to retain the ''blanket rule'' protections or to promulgate a species-specific 4(d) rule that may include some or all of the section 9 prohibitions instead. At that point, we continue to have an ''almost infinite number of options'' (H. Rep. 93–412, at 12 (1973)), including the option of applying the ''blanket rule,'' with regard to protecting the species through prohibitions and exceptions. Therefore, even if Congress did intend for the Service to issue species-by-species protective regulations, developing these ''blanket rules'' does not conflict with that intent. Finally, as we made clear during our rulemaking in 2019 ending the ''blanket rule'' option for species newly listed as threatened species after the effective date of those regulatory revisions, either approach (using ''blanket rules'' or requiring promulgation of species-specific 4(d) rules for every species listed as threatened species) is consistent with the Act ([84 FR 44753 at 44754, August 27, 2019] (citing *Sweet Home Chapter of Communities for a Great Oregon* v. *Babbitt,* 1 F.3d. 1, 8 (D.C. Cir. 1993), *modified on other grounds on reh'g,* 17 F.3d 1463 (D.C. Cir. 1994), *rev'd on other grounds,* 515 U.S. 687 (1995)).

Comment 3: Some commenters suggested that the ''blanket rules'' represent a default precautionary approach to protecting threatened species and that such a precautionary approach or using a worst-case scenario is contrary to *Maine Lobstermen's Ass'n* v. *NMFS,* 70 F.4th 582, 599 (D.C. Cir. 2023) (*MLA*).

Response: We note at the outset that the *MLA* case involved a different situation that does not apply here because that case arose in the context of section 7, not section 4, of the Act. The holding of *MLA* is limited to the conclusion that the particular biological opinion before the Court in that case was unlawful because in deciding

whether the proposed action was ''likely to jeopardize the continued existence of'' a listed species within the meaning of section 7, it applied worst-case assumptions without first analyzing whether those assumptions were scientifically appropriate in light of the information available to NMFS. The court characterized the NMFS's argument as insisting that legislative history required that, in order to ''give the benefit of the doubt to the species,'' or apply a precautionary principle, the Services must rely upon ''worst-case scenarios'' in the face of scientific uncertainty (*MLA,* 70 F.4th at 586, 597). The ''blanket rules'' implement section 4 of the Act, not section 7, and as discussed below the bases for the ''blanket rules'' are completely different from the court's characterization of the bases underlying the biological opinion in the *MLA* case. We are not claiming that legislative history requires us to promulgate the ''blanket rules'' in order to ''give the benefit of the doubt to the species.'' Nor are the ''blanket rules'' based on ''worst-case scenarios.'' Rather, we are promulgating the ''blanket rules'' in order to advance the efficient fulfillment of our responsibility under the Act to conserve threatened species. All threatened species, by definition, are likely to become in danger of extinction within the foreseeable future, and these species often need protections like the provisions in the ''blanket rules'' to recover them. In the time since the 2019 4(d) rule went into effect, nearly all of the species-specific 4(d) rules that the Service has promulgated have concluded that all of the section 9 prohibitions and the standard exceptions to those prohibitions provided for in the ''blanket rules'' are necessary and advisable to provide for the conservation of the species. In most cases, we also included one or more additional exceptions to those prohibitions. (As stated earlier, although the second sentence of section 4(d) does not require us to make a ''necessary and advisable'' finding to adopt for a threatened species one or more of the prohibitions that apply to endangered species under section 9, we have chosen to determine that each 4(d) rule in its entirety provides the protections that are necessary and advisable to provide for the conservation of that species.)

Comment 4: Several States expressed appreciation for the inclusion of the exceptions for States with cooperative agreements to conduct conservation actions. The regulatory text includes these exceptions as a default for all future species-specific 4(d) rules, as well as for any species currently or in the future protected by ''blanket rules'' at 50 CFR 17.31(a) and 17.71(a). Other commenters expressed concern about the treatment of States in reinstatement of the ''blanket rules.'' Commenters suggested that ''blanket rules'' ignore the sovereignty of the States and give short shrift to the expertise of States and State agencies to manage their resources effectively and efficiently and preferred that we only use species-specific 4(d) rules as they incentivize State input and give States more authority for management of threatened species. Several commenters stated that putting in place ''blanket rules'' that give threatened species the same protections as endangered species would interfere with the role that Congress intended for States to take in safeguarding species. They argued that giving threatened species the same protections as endangered species would have the effect of reducing the incentives for States and landowners to be proactive in improving the status of endangered species in an effort to reduce the severity of the prohibitions applicable to the species. As evidence that Congress intended a more active role for States, some of the commenters pointed to references to ''federalism'' in the legislative history.

Response: We recognize the authorities given to States in section 6 of the Act to conserve listed species and the partnership among the Service and the States in conserving federally listed species. As stated in our ''Revised Interagency Cooperative Policy Regarding the Role of State Agencies in Endangered Species Act Activities'' (81 FR 8663, February 22, 2016), it is our practice to use the expertise of, and coordinate and collaborate with, State agencies in developing the scientific foundation upon which the Services base their determinations for listing actions, including 4(d) rules that specify the prohibitions necessary and advisable for the conservation of species listed as threatened. We note that the preemptive effect of the Act and implementing regulations in part 17 with regard to State laws for endangered species or threatened species is pursuant to section 6(f) of the Act. (See 16 U.S.C. 1535(f); the Supremacy Clause of the U.S. Constitution; *H.J. Justin & Sons, Inc.* v. *Deukmejian,* 702 F.2d 758, 759–60 (9th Cir. 1983); *Man Hing Ivory & Imports, Inc.* v. *Deukmejian,* 702 F.2d 760 (9th Cir. 1983); *Cresenzi Bird Importers, Inc.* v. *New York,* 658 F. Supp. 1441, 1444–46 (S.D.N.Y.), *summarily aff'd,* 831 F.2d 410 (2d Cir. 1987).) In summary, by operation of the express preemption clause of the Act's section 6(f), and the U.S. Constitution's Supremacy Clause, where a species is listed as an endangered species or a threatened species under the Act, any State law or regulation that applies with respect to the importation or exportation of, or interstate or foreign commerce in, endangered species or threatened species is void to the extent that it may effectively allow or permit what is prohibited by the Act or implementing regulations for endangered species or threatened species, or prohibit what is authorized pursuant to an ESA exemption or implementing regulations or permits for endangered species or threatened species. For species under the jurisdiction of the Service, implementing regulations and permits for endangered species or threatened species are provided for in part 17. Additionally, any State law or regulation respecting the taking of an endangered species or threatened species, or activities with unlawfully taken endangered species or threatened species, may be more restrictive, but not less restrictive, than Act exemptions or implementing regulations or permits for endangered species or threatened species provided for in part 17. Pursuant to section 6(f) of the Act, part 17 shall not otherwise be construed to void any State law or regulation that is intended to conserve fish or wildlife, or to permit or prohibit sale of fish or wildlife within the jurisdiction of a State.

The exceptions included in both the ''blanket rules'' and species-specific 4(d) rules for States to take federally listed threatened species in the course of carrying out conservation programs recognizes this authority and these partnerships. While we recognize and value the important role States play in conserving both endangered and threatened species, the Act requires that the Service issue protective regulations necessary and advisable for threatened species along with several other requirements to conserve threatened species (*e.g.,* designating critical habitat, developing recovery plans, consulting with Federal agencies on their discretionary actions). We have concluded that reinstating the ''blanket rules'' would neither reduce incentives on the part of States to undertake proactive conservation efforts nor interfere with the congressional approach to federalism and the States' role in conservation through the Act. Even with the ''blanket rules'' in place, State programs would still have the opportunity and the incentive to undertake proactive conservation for species under their jurisdiction to

improve the species' status and potentially avoid the need for the Service(s) to list a species or to help achieve recovery of the species should it be listed. In addition, the Service would consider any such State efforts when it decides whether to protect a species by a ''blanket rule'' or to promulgate a species-specific 4(d) rule.

We note that the exceptions from threatened species permitting requirements for certain activities by employees or agents of the Service and certain other Federal, State, and Tribal entities under 50 CFR 17.31(b) and 17.71(b) do not remove the need for entities to comply with other laws and regulations. As with other exceptions from endangered or threatened species permitting requirements in 50 CFR part 17, these limited exceptions allow for the specified otherwise prohibited activities under the Act to occur without a permit under part 17. Permitting exceptions in part 17 are only in relation to ESA prohibitions for endangered and threatened species and the permitting requirements under part 17 and should not be construed to relieve a person from requirements of other parts in subchapter B, or any other applicable laws or regulations other than as provided by section 6(f) as described above. We take this opportunity to note that 50 CFR 10.3 provides that no statute or regulation of any State shall be construed to relieve a person from the restrictions, conditions, and requirements contained in subchapter B. In addition, nothing in subchapter B, nor any permit issued under subchapter B, shall be construed to relieve a person from any other requirements imposed by a statute or regulation of any State or of the United States, including any applicable health, quarantine, agricultural, or customs laws or regulations, or other Service enforced statutes or regulations.

Comment 5: Several commenters stated that we did not provide enough justification or logical rationale for the reinstatement of the ''blanket rules.'' For example, one commenter stated that the Service needs to explain how the 2019 4(d) rule was inconsistent with, or otherwise presented obstacles to, the policy articulated by Executive Order 13990. Other commenters suggested that we did not comply with the Administrative Procedure Act (APA). Of these, one commenter stated that we failed to conduct required outreach ''in conformance with the requirements of the Administrative Procedure Act'' including ''reaching out to, and consulting directly with, non-Federal sponsors of projects and the communities they help to protect so these rules can be developed cooperatively, using objective criteria and approaches.'' Some commenters stated that, at a minimum, the Service has not shown that there are good reasons for the new policy (see *FCC* v. *Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (*FCC* v. *Fox*)).

Response: We have complied fully with the APA. We published notice of the proposed rulemaking in the **Federal Register**, we provided an opportunity for public comment, we considered the relevant matter presented in those comments, and we have provided a rational explanation for our action. The APA does not require the specific outreach suggested by a commenter. In addition, as discussed elsewhere, while not required, we held six informational sessions for a wide variety of audiences and over 500 attendees participated in these sessions.

In our 2019 4(d) rule (84 FR 44753–44754, August 27, 2019), we explained that we were ending the ''blanket rule'' option for application of section 9 prohibitions to species newly listed as threatened species after the effective date of those regulatory revisions because: It would make our regulatory approach for threatened species similar to NMFS's approach; either using ''blanket rules'' or promulgating species-specific rules is a reasonable approach to implementing the Secretary's discretion afforded under section 4(d) of the Act; and promulgating species-specific 4(d) rules that are tailored to the specific species can provide conservation benefits for threatened species. After several years of experience operating under the 2019 4(d) rule, we now find—as explained further in our preambles to the June 22, 2023, proposed rule (88 FR 40742 at 40743–40745) and this final rule—that reinstating the ''blanket rule'' option is preferable to requiring promulgation of species-specific 4(d) rules every time we list a species as a threatened species. As we recognize throughout this final rule, we do not discount the importance of our ability to promulgate species-specific 4(d) rules. However, it is important for us to once again have the option of applying the ''blanket rules'' when appropriate. In summary, we have found that it makes sense to reinstate ''blanket rules'' that facilitate the application of the Act's section 9 prohibitions to threatened species because ''blanket rules'' allow for a more-efficient method to protect threatened species for which we find their protections are appropriate. In addition, it is more straightforward and transparent to have species-specific 4(d) rules in one place in the Code of Federal Regulations and ''blanket rule'' protections described in another, as we have done for 40 years. Finally, the reinstatement of the ''blanket rules'' also ensures there is never a lapse in threatened species protections. This is sufficient explanation under the Supreme Court's decision in *FCC* v. *Fox* (556 U.S. at 515 (''[I]t suffices that [this policy choice] is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better, which the conscious change of course adequately indicates.'' (Emphasis in original))).

Executive Order 13990 required all agencies to review agency actions issued between January 20, 2017, and January 20, 2021, that may be inconsistent with the policies it set forward. Following the issuance of that E.O., we undertook a review of the 2019 4(d) rule revoking the prior blanket rules. E.O. 13990 provided the impetus for the review, but the E.O. is not the legal basis of the revision. We are revising our regulations at 50 CFR part 17 on the basis of our legal authority under the Act (16 U.S.C. 1531 *et seq.*).

Comment 6: Multiple commenters suggested that by reinstating ''blanket rules'' we fail to recognize the benefits of species-specific 4(d) rules. Several commenters also requested that we continue to promulgate species-specific 4(d) rules.

Response: As stated in the preambles to the June 22, 2023, proposed rule (88 FR 40742 at 40745) and this final rule, we maintain in our regulations at 50 CFR 17.31(c) and 17.71(c) the ability to issue species-specific 4(d) rules. We do not deny the benefit of species-specific 4(d) rules as we referenced in our 2019 4(d) rule. As noted elsewhere in this document, species-specific 4(d) rules can incentivize known beneficial actions for the species by removing or reducing regulatory burden associated with those actions and can also remove or reduce regulatory burden associated with permitting of otherwise prohibited actions or forms or amounts of ''take'' considered inconsequential to the conservation of the species. Species-specific 4(d) rules should apply protections that will both prevent the species from becoming endangered and promote the recovery of species.

Comment 7: A commenter suggested that the Service does not need ''blanket rules'' because we can promulgate a species-specific 4(d) rule to adopt the same endangered species prohibitions.

Response: While we can and have done what the commenter suggested, it is more straightforward and transparent to have species-specific 4(d) rules in one place in the Code of Federal Regulations

and ''blanket rule'' protections described in another, as we had for the 40 years prior to September 26, 2019. Any threatened species not included at 50 CFR 17.40 through 17.48 (for wildlife) or 17.73 through 17.78 (for plants) has the ''blanket rule'' protections. We will clearly state in proposed and final rules for each species whether there is a species-specific 4(d) rule or whether the species is protected under 50 CFR 17.31(a) (wildlife) or 17.71(a) (plants).

Comment 8: Several commenters suggested that reinstating the ''blanket rule'' options will further the recovery of threatened species. For example, one commenter suggested ''blanket rules'' provide more incentives for landowners and land managers to recover endangered species. We also received comments suggesting the opposite. For example, commenters suggested that ''blanket rules'' collapse the distinction between endangered and threatened species and diminish incentives for private property owners and other regulated entities to take actions that would result in the reclassification of a species from an endangered species to a threatened species. They suggest there would be no functional difference between an endangered species and a threatened species because the same protections could apply uniformly absent a species-specific rule.

Response: We disagree that reinstating the ''blanket rule'' options for threatened species influences whether the Services and our partners implement actions to recover endangered species. Further, all 4(d) rules, whether ''blanket rules'' or species-specific rules, play a role in recovering threatened species, since the statute requires that 4(d) rules be necessary and advisable to provide for the conservation of threatened species. Even with the ''blanket rule'' option, there are incentives for certain entities to conduct conservation actions for endangered species because ''blanket rule'' protections for threatened species include additional exceptions beyond those provided in our regulations for endangered species. In addition, we always have the option of promulgating species-specific 4(d) rules for any threatened species whose status improves as a result of conservation actions.

We anticipate promulgating species-specific 4(d) rules for most wildlife species when they are reclassified from an endangered species to a threatened species because we will have had many years of experience in determining how best to manage a species in that situation. Given the narrower protections for endangered and threatened species of plants, it may make sense in many cases for the Service to use ''blanket rule'' protections for plants reclassified from endangered species to threatened species.

Comment 9: Commenters stated that ''blanket rules'' will impose burdensome costs and regulatory requirements on both the Service and the regulated community. They suggested that reliance on the ''blanket rules'' will lead to an increased need for permitting by project proponents, taxing both project proponents and the Service, who will have to process and administer additional permits, as well as increasing the degree to which the Service must use its resources to enforce the prohibitions of section 9 of the Act. They also suggested that reinstatement of the ''blanket rules'' will, in fact, add to the agency's regulatory burden with an increase in the number of entities applying for section 10 authorization or seeking project-by-project coordination on issues that could have been adequately addressed pursuant to a species-specific 4(d) rule.

Response: As stated elsewhere in this document, for each threatened species we will either protect that species with ''blanket rule'' protections or a species-specific 4(d) rule depending on what is necessary and advisable to provide for the conservation of the species. For most currently listed threatened species, regardless of protections under ''blanket rule'' or species-specific regulations, we have included all of the section 9 prohibitions as well as exceptions to those prohibitions, such as allowing ''take'' of threatened species of wildlife in defense of life or other issues of human safety, for law enforcement activities, for aiding injured or diseased individuals or disposing of dead individuals, and for conservation actions conducted by specific entities.

We do not envision that 4(d) rules will wholly replace the need for section 10 permits for most species. It is appropriate to continue to require recovery permits for otherwise prohibited acts in situations in which we must understand the qualifications and methods of the proposed recovery action. It is often similarly appropriate to continue to prohibit incidental take and issue permits under section 10(a)(1)(B) of the Act for take that is associated with threats that individually or cumulatively led to the listing of the species (or may be new threats to the species) so that project proponents and the Service can determine approaches to minimize and mitigate the impact of the take. Programmatic approaches are available for project proponents to reduce the time associated with developing permit applications such as general conservation plans and template habitat conservation plans. In addition, the Service and project proponents can reduce the need for such permits by developing standardized conservation measures to avoid the risk of ''take.''

Comment 10: One commenter agreed with our intention to implement the revised regulations on a prospective basis because they suggest it would avoid any confusion as to the management of already listed species.

Response: As discussed in the preamble of this rulemaking and to clarify here, reinstating the ''blanket rule'' option and other regulation revisions will result in minor changes to protections for currently listed threatened species, whether those species received 4(d) protections from the prior versions of the ''blanket rules'' or from a species-specific 4(d) rule. Species that were protected under prior versions of the ''blanket rules'' or under species-specific 4(d) rules that refer to any of the sections we are revising will receive the updated protections for any actions occurring after the effective date of this rule (see **DATES**, above). Applying the revised prohibitions and exceptions makes only two substantive changes to the protections for those previously listed threatened species. First, we have added federally recognized Tribes to the entities authorized to aid, salvage, or dispose of threatened species. Second, as a result of updating our endangered plant regulations at 50 CFR 17.61(c)(1) to match amendments to the Act that Congress enacted in 1988, threatened plants protected under the previous ''blanket rule'' are now protected from being maliciously damaged or destroyed on areas under Federal jurisdiction, or being removed, cut, dug up, or damaged or destroyed on any other area in knowing violation of any law or regulation of any State or in the course of any violation of a State criminal trespass law. The remaining changes are minor wording revisions or clarifications.

Comment 11: Several commenters suggested that we reevaluate current protections for threatened species (species currently protected under ''blanket rules'' or species-specific 4(d) rules).

Response: Although we have the discretion to revise protections for threatened species at any time, evaluating or reevaluating the protections for particular species is outside the scope of this rulemaking. Every species that is listed as a threatened species under the Service's

jurisdiction is currently benefitting from protective provisions in a 4(d) rule. Species that were listed after the effective date of the 2019 4(d) rule (September 26, 2019) are all protected by species-specific 4(d) rules; species that were listed before the effective date of the 2019 4(d) rule are, and will continue to be, protected either by the ''blanket rule'' protections or by a species-specific 4(d) rule. For species that are currently protected by species-specific 4(d) rules, reinstating the ''blanket rules'' will have no effect because the species will continue to be protected by the previously promulgated species-specific 4(d) rules. In addition, as discussed elsewhere in this document, for species that are currently protected by the prior ''blanket rules,'' these ''blanket rules'' make only two substantive changes: (1) adding federally recognized Tribes to the entities authorized to aid, salvage, or dispose of threatened species; and (2) updating the protections for threatened plants. Therefore, there is nothing in these narrow changes that requires us to reevaluate current protections for already listed threatened species. In the future, we may still determine that it is appropriate to reevaluate the protective 4(d) regulations for particular threatened species.

Comment 12: Several commenters stated that species-specific 4(d) rules streamline the Act's section 7 consultation process for future Federal actions. They find that species-specific 4(d) rules help identify specific actions or activities that may be undertaken without impairing the listed species' conservation and protection, allowing project proponents to tailor their activities to avoid excessive or unnecessary take based on the contents of the species-specific 4(d) rule.

Response: Regardless of whether a threatened species is protected via ''blanket rule'' protections or a species-specific 4(d) rule, responsibilities under section 7 of the Act for Federal agencies to consult with the Services for actions that ''may affect'' a federally listed species or designated critical habitat apply. In the future, we will continue to develop species-specific 4(d) rules for many threatened species, and for others we will use ''blanket rule'' protections. With or without species-specific 4(d) rules, there are mechanisms to streamline section 7 consultations, including programmatic consultations and developing standardized conservation measures.

Comment 13: Several commenters suggested a blanket 4(d) rule has the potential to discourage species conservation efforts abroad. For example, a commenter noted zoos holding such species may be required to obtain new or additional permits from the Service to authorize import, export, and other otherwise-prohibited activities, which would incur time and permitting fees for applicants and processing time and costs for the Service. Another commenter asserted that establishing blanket prohibitions on trade would remove any incentive to develop captive-breeding programs and have a disastrous effect on wild populations of a listed species. Some comments related to discouraging conservation efforts resulting from well-managed hunting of foreign species listed under the Act. They asserted that a blanket 4(d) rule could impair or eliminate the ability of American hunters to import legally harvested hunting specimens of threatened species acquired abroad. In their view, such restrictions would negatively impact foreign wildlife management agencies that rely on hunting revenue for significant portions of their budgets. They additionally asserted that establishing protections under a ''blanket rule'' may undermine conservation efforts for foreign species taken under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

Response: The purpose of CITES is to regulate international trade in plants and animals to ensure such trade is legal and does not threaten the survival of species in the wild. In determining the status of a species under the Act or the protective regulations that it needs, we take into consideration any protection provided by other laws, such as CITES. However, simply being protected by these other laws does not preclude the need to list a species under the Act if it meets the Act's definition of an endangered or threatened species. Additional conservation measures are provided to species listed as endangered or threatened under the Act, including recognition, requirements for Federal protection, and prohibitions against certain activities with the species. Recognition through listing results in public awareness and may encourage and result in conservation actions by foreign governments; Tribal entities; Federal, State, and local agencies; private agencies and interest groups; and individuals. For example, listing a species under the Act can support the conservation efforts undertaken for the species in its range, including research efforts to address conservation needs and funding and other assistance to foreign countries to provide for the conservation of endangered species and threatened species. Listing under the Act can also help ensure that the United States and its citizens do not contribute to the further decline of the listed species through resulting Federal protections and prohibitions on certain activities such as import, export, take, interstate commerce, and foreign commerce. For instance, adding a violation under the Act on top of a CITES violation could serve as an additional disincentive for any illegal trade in the species.

We acknowledge that in well-managed circumstances some captive-breeding activities can contribute to the conservation of endangered or threatened species in the wild if, for example, they are part of a genetically managed conservation breeding program producing animals that could be used for reintroductions. We also acknowledge that well-managed trophy hunting can generate funds to be used for conservation, including for habitat protection, population monitoring, wildlife management programs, mitigation efforts for human–wildlife conflict, and law enforcement efforts. Persons seeking to engage in otherwise prohibited activities with threatened wildlife for scientific purposes or to enhance the propagation or survival of these species may still seek authorization from the Service through threatened species permits (see 50 CFR 17.32) or captive wildlife registration (see 50 CFR 17.21(g)) as applicable.

Comment 14: Operation of the ''blanket rule'' impairs conservation of threatened species hunted abroad, when the import of a hunting trophy would otherwise not require an import permit under the existing import exemption for threatened species (CITES Appendix-II wildlife at 50 CFR 17.8) and when a threatened species is not listed under CITES.

Response: Nothing in this rulemaking affects the operation of 50 CFR 17.8. The only changes to 50 CFR 17.8 we are finalizing are technical corrections, as proposed, that would merely update the terminology ''special rule'' to ''species-specific rule'' for consistency with similar corrections we are making in other sections of part 17. As a result, section 9(c)(2) of the Act and our implementing regulations at 50 CFR 17.8 continue to provide the limited exception to the § 17.31 prohibition against the importation of threatened wildlife for species that are also included in CITES Appendix-II (provided that the other requirements of 50 CFR 17.8(b) are met).

However, as is always the case, the exception at 50 CFR 17.8 to the

prohibition on importation in the ''blanket rule'' does not apply to threatened wildlife subject to a species-specific 4(d) rule (see 50 CFR 17.8(b)). Therefore, if we issue a species-specific 4(d) rule for a particular species, all of the prohibitions and exceptions for that species are contained in the species-specific rule, and the presumption that otherwise qualifying imports do not require a threatened-species permit is rebutted. If the species-specific 4(d) rule prohibits import and does not contain an applicable exception, any would-be importer of that species would be required to obtain an authorization or permit under the Act prior to import (see *Safari Club Int'l* v. *Zinke,* 878 F.3d 316, 328–29 (D.C. Cir. 2017); see also *Safari Club Int'l* v. *Babbitt,* No. MO–93–CA–001, 1993 U.S. Dist. LEXIS 21795, 1993 WL 13932673 (W.D. Tex. Aug. 12, 1993)). As the D.C. Circuit held in *Safari Club,* ''[s]ection 9(c)(2) in no way constrains the Service's section 4(d) authority to condition the importation of threatened Appendix II species on an affirmative enhancement finding. Under section 4(d) of the Act, the Service 'shall issue such regulations as [it] deems necessary and advisable to provide for the conservation of [threatened] species' and may 'prohibit with respect to any threatened species any act prohibited . . . with respect to endangered species,' see 16 U.S.C. 1533(d). Because the Service may generally bar imports of endangered species, *see id.* [section] 1538(a)(1)(A), it may do the same with respect to threatened species under section 4(d), *see id.* [section] 1533(d).'' The D.C. Circuit went on to explain that ''promulgation of a blanket ban would be permissible and rebut the presumptive legality of elephant imports. If the Service has the authority to completely ban imports of African elephants by regulation under section 4(d), it logically follows that it has authority to allow imports subject to reasonable conditions, as provided in the [species-specific 4(d) rule for African elephants].''

In other words, if a species-specific 4(d) rule prohibits import, then the limited exception at 50 CFR 17.8 to the requirement for import permits does not apply to the species, and an import permit is required unless the species-specific 4(d) rule provides a separate exception. The limited exception to the requirement for import permits also does not apply if the threatened wildlife is not listed under CITES or is listed under CITES Appendix I. These issues are further explained in the 2006 proposed rule and 2007 final rule promulgating 50 CFR 17.8 (see 71 FR 20168 at 20170–20171, April 19, 2006 (''[I]t is important to note that if a threatened species . . . has a special rule, proposed section 17.8 does not apply; the provisions of the special rule apply.''); and 72 FR 48402 at 48404–48405, August 23, 2007 (''This exemption does not apply to species that have a special rule in 50 CFR part 17.'')).

The application of the ''blanket rule'' to a species of threatened wildlife, on the other hand, does not affect the operation of 50 CFR 17.8 for qualifying imports. When applied to a threatened species, the ''blanket rule'' includes a prohibition on import under 50 CFR 17.31 unless a threatened species import permit is issued under 50 CFR 17.32. An exemption to the threatened species import permit requirement of the ''blanket rule'' is granted under the limited circumstances provided at 50 CFR 17.8 for qualifying imports of CITES Appendix-II wildlife. Accordingly, for threatened species of wildlife protected by the ''blanket rule'' that are also included in Appendix II of CITES, the limited 50 CFR 17.8 exemption to the requirement to obtain import permits for threatened species applies to specimens that meet all the requirements of 50 CFR 17.8(b).

Comment 15: Several commenters requested that the Service include additional exceptions or requirements applicable to either the ''blanket rules'' or all future species-specific 4(d) rules. Examples of exceptions include exceptions for anyone conducting maintenance of existing infrastructure or conducting conservation-related efforts or aiding or salvaging threatened species. We also received requests to include exceptions for specific entities conducting conservation efforts or aiding or salvaging threatened species.

Some commenters recommended that we require States or Federal land managers to submit proposals before being allowed to use the current exception to take an individual member of a listed species that poses a demonstrable but non-immediate threat to human safety. Other commenters suggested that we revise regulations to require that: (1) 4(d) rules act as a recovery roadmap with triggers to reduce regulation over time; (2) species-specific 4(d) rules provide a ''net conservation benefit'' to the species; (3) species-specific 4(d) rules require mitigation associated with excepted actions or take; and (4) the Service commits to reevaluate 4(d) rules when we complete a recovery plan.

Response: We appreciate these additional suggestions and decline to include any additional exceptions or requirements that would apply to all future threatened species. However, it may be appropriate to include some of the suggested exceptions in species-specific 4(d) rules, and we can evaluate that possibility for specific species in the future based on the facts and circumstances for those species. Regarding the ''net conservation benefit'' standard, we already have a standard under the Act, and that is to craft regulations that are necessary and advisable for the conservation of the species. Regarding the suggestion to require mitigation within all 4(d) rules for any excepted activities or take, we disagree that this is appropriate to require this either for the ''blanket rules'' or for future species-specific rules. As discussed elsewhere in this document, we include several exceptions to otherwise prohibited take in our ''blanket rules.'' These include exceptions for allowing take in defense of life or other issues of human safety, for law enforcement activities, for aiding injured or diseased individuals or disposing of dead individuals, and for conservation actions conducted by specific entities, and none of these require mitigation. In addition, in our species-specific rules, we include exceptions that should help incentivize beneficial actions for the species by removing or reducing regulatory burden associated with those actions; we can also remove or reduce regulatory burden associated with permitting of otherwise prohibited actions or forms or amounts of ''take'' considered inconsequential to the conservation of the species. Because the take associated with the activities in the exceptions is either beneficial or de minimis, requiring mitigation for these exceptions is unnecessary. Finally, the Service can revisit protections for threatened species at any time, including after completion or revision of a recovery plan.

Comment 16: Several commenters expressed concern that we intend to apply ''blanket rules'' to experimental populations listed as threatened species under section 10(j) of the Act.

Response: In the preamble of the June 22, 2023, proposed rule (88 FR 40742 at 40747), we stated that, pursuant to 50 CFR 17.81, experimental populations are designated through population-specific regulations found in §§ 17.84 through 17.86, and under our existing practice, each population-specific regulation contains all of the applicable prohibitions, along with any exceptions to prohibitions, for that experimental population. Further, our regulations at 50 CFR 17.81(f) state that any population of an endangered species or a threatened species determined by the

Secretary to be an experimental population in accordance with subpart H of part 17 will be identified by a species-specific 4(d) rule in §§ 17.84 and 17.85 as appropriate and separately listed in § 17.11(h) (wildlife) or § 17.12(h) (plants) as appropriate. Per those regulations, all experimental populations will have species-specific 4(d) rules.

Plants

Comment 17: Several commenters supported our proposal to update regulations for endangered plants to include making it unlawful to maliciously damage or destroy the species on any area under Federal jurisdiction; or remove, cut, dig up, or damage or destroy the species on any other area in knowing violation of any law or regulation of any State or in the course of any violation of a State criminal trespass law. Another commenter thought the proposed wording would expand and clarify the actions currently in § 17.61(c) that are prohibited without a permit, better comply with the Act (as amended), better implement Congress's intent, and provide greater conservation benefit to endangered plants. In contrast, several other commenters opposed this proposed change because they stated the Act does not allow for the new language. They stated that the plain language of the definition of ''take'' does not apply to either an endangered plant or a threatened plant, yet the proposed rule seemingly intends to sanction an apparent ''take'' of such species in direct contradiction to the Act, and that the Service should not promulgate a rule inconsistent with the plain language of the applicable statute.

Response: The intent of revising this portion of the regulations is to bring the regulatory protections afforded to endangered plants in alignment with the protections already provided by section 9(a)(2)(B) of the Act (16 U.S.C. 1538(a)(2)(B)). The Act does not contain a prohibition against ''take'' of endangered plants in section 9(a)(2) that is equal to its prohibition against take of endangered fish and wildlife in section 9(a)(1)(B) and (C). However, with respect to endangered plants, the amendments to the Act that Congress enacted in 1988 (16 U.S.C. 1538(a)(2)(B); Act section 9(a)(2)(B), Public Law 100–478 (October 7, 1988)) included additional text in section 9(a)(2)(B) making it unlawful to maliciously damage or destroy the endangered plant species on any area under Federal jurisdiction; or remove, cut, dig up, or damage or destroy the species on any other area in knowing violation of any law or regulation of any State or in the course of any violation of a State criminal trespass law. In this final rule, we add this same text to our regulations at § 17.61(c). To clarify our intent, in the preamble of this final rule, we emphasize that this particular revision merely brings our regulations into alignment with the Act.

Comment 18: Some commenters stated that the following proposed language in 50 CFR 17.61(c) and 17.71(b) is confusing: ''may, when acting in the course of official duties, remove and reduce to possession from areas under Federal jurisdiction those species.''

Response: We note that the referenced language at 50 CFR 17.61(c)(2) and 17.71(b)(3) is slightly different than the language quoted by the commenter but matches the language currently in the Code of Federal Regulations at 50 CFR 17.61(c)(2) and our regulation revisions do not change that language. We are revising our regulations to include the same language at 50 CFR 17.71(b)(3). We regret that the noted language is confusing to commenters, but this text comes directly from the 1988 amendments to the Act (Pub. L. 100–478 (October 7, 1988)), and by including it in our regulations, we align our regulations with the Act. The exception allows for specified entities to remove (from areas under Federal jurisdiction) and reduce to possession endangered or threatened species of plants without the need for a permit under the Act.

Comment 19: Many commenters supported updating protections for plants listed as threatened species. However, other commenters opposed the updates because they believed that existing regulations adequately protect threatened species of plants and stated that the revisions may create confusion regarding compliance by creating a risk of enforcement where none existed before.

Response: In the past, the public has expressed confusion about what statutory and regulatory protections apply to threatened species of plants. The plain language of section 4(d) of the Act indicates that the Secretary may by regulation prohibit acts to threatened species of plants similar to those prohibited for endangered plants under section 9(a)(2). As discussed in the preamble of this document, we have concluded that providing an option to apply those prohibitions to threatened species of plants is necessary and advisable unless we promulgate a species-specific 4(d) rule for that species. As for wildlife species, having consistent prohibitions for plant species should reduce confusion regarding compliance.

Comment 20: Some commenters were concerned about the insertion of the text ''knowing violation of any law or regulation of any State or in the course of any violation of a State criminal trespass law'' at 50 CFR 17.61(c). The commenters noted that the proposed rule does not identify or give an example as to what ''any law or regulation of any State'' may be; and assuming any such law or regulation exists in a State, the proposed revisions do not exempt a well-meaning person unaware of the presence of listed species. The commenters stated it is not reasonable to label an inadvertent removal, cutting, digging up, damage, or destruction of a species as a violation, and that innocent, inadvertent behavior should not be subject to sanction.

Response: As noted elsewhere in this document, the intent of revising this portion of the regulations is to bring the regulatory language into alignment with section 9(a)(2)(B) of the Act (16 U.S.C. 1538(a)(2)(B)). These protections for endangered plants have been in place since the 1988 amendments to the Act, and they do not prohibit ''inadvertent'' impacts from well-meaning people; they only prohibit acts that someone commits ''in knowing violation'' of the law.

With regards to the request for an example of a State law that may be applicable, one example would be a law that prohibits impacts to a State-listed plant species that is also federally listed. For example, Oregon Revised Statute (ORS) 564.120, titled ''Transactions in threatened or endangered species; restrictions; prohibition,'' is under the section of State law titled ''Threatened or Endangered Plants,'' and it reads in part that ''Except as otherwise provided pursuant to ORS 564.105, no person shall take, import, export, transport, purchase or sell, or attempt to take, import, export, transport, purchase or sell any threatened species or endangered species.''

Comment 21: Many commenters suggest that we will not determine whether the ''blanket rule'' is appropriate for a given species at the time of listing but simply default to blanket protections. Several commenters were concerned that we will rarely use species-specific 4(d) rules if we have the ''blanket rule'' option in place. Commenters suggested that because the ''blanket rule'' adopts a ''one size fits all'' approach for all threatened species, this approach creates additional burdens for the regulated public. Other commenters stated that for newly listed threatened species, we should clearly

indicate whether the ''blanket rule'' or a species-specific 4(d) rule will apply.

Response: For every threatened species, when we list that species, we will determine what protections are appropriate. We also intend to clearly state what protections apply for a listed species in each proposed and final listing rule.

For threatened species of plants, we expect that we may use ''blanket rules'' frequently because the prohibitions for plants under the Act are narrower than those for wildlife, likely resulting in fewer options for exceptions to those prohibitions. However, for wildlife species, we expect to continue to routinely use both species-specific 4(d) rules and the ''blanket rule.'' Finalizing these regulations will allow us the flexibility to apply the appropriate protective regulations in the most efficient manner based on the best available scientific and commercial information.

Comment 22: Several commenters suggest that when using the ''blanket rule'' protections, threatened species will be treated the same as endangered species, resulting in overregulation.

Response: The Act's section 9 prohibitions that apply to an endangered species will also apply to a threatened species when we use the blanket rule. As discussed above, our endangered species regulations also include a suite of exceptions, which allow for various entities to conduct otherwise prohibited acts without a permit under the Act (*e.g.,* any person may take endangered wildlife in defense of their own life or the lives of others; Federal and State law enforcement officers may possess, deliver, carry, transport, or ship any endangered wildlife taken in violation of the Act as necessary in performing their official duties; certain individuals can take wildlife to aid, salvage, or dispose of endangered species). Protections for threatened species under the ''blanket rules'' also include these standard exceptions; however, because threatened species are not in danger of extinction but are likely to become so within the foreseeable future, we provide additional flexibility for managing threatened species. At 50 CFR 17.31(b) and 17.71(b), we include for threatened species exceptions that are more numerous or broader than those for endangered species. These include additional exceptions for the Service and NMFS to conduct otherwise prohibited acts without a permit under the Act associated with carrying out conservation actions and broader exceptions for agents or employees of State conservation agencies operating a conservation program in accordance with section 6(c) of the Act to conduct otherwise prohibited acts without a permit under the Act. Therefore, we are not treating threatened species the same as endangered species, and the ''blanket rule'' does not result in overregulation.

Comment 23: Several commenters suggest that we continue with (or commit to) issuing species-specific 4(d) rules concurrently with threatened species listings, as doing so would ease the Service's administrative burden by ensuring the Service only has to receive and respond to one round of public comments and finalize one rulemaking as opposed to two.

Response: When we determine that species-specific 4(d) rules are appropriate, we intend to finalize those species-specific 4(d) rules concurrently with final listing rules. We agree this approach is the most efficient. Similarly, when we do not promulgate a species-specific 4(d) rule, and thereby provide for the conservation of the species through the blanket rule, those protections too will occur concurrently with the final listing rule.

Comment 24: Some commenters expressed concern that reinstating the ''blanket rules'' will result in inconsistency between the Service and NMFS, creating unnecessary confusion for the regulated community and the public about how the Act's section 4(d) is implemented. At least one commenter suggested that species with overlapping jurisdiction would result in unintended consequences that could negatively affect the species.

Response: As discussed in the preamble to the June 22, 2023, proposed rule (88 FR 40742 at 40745), we recognize that reinstating the ''blanket rules'' will again result in different approaches to protecting threatened species under the Act. NMFS does not have ''blanket rules'' for threatened species; therefore, NMFS approaches each species on a case-by-case basis based on the discretion afforded under section 4(d) and promulgates species-specific 4(d) rules at 50 CFR part 223. The Service will continue to maintain the option to promulgate species-specific 4(d) rules and will determine the appropriate protections for each species at the time of listing. Given that our agencies applied these different approaches for more than 40 years beginning early in the administration of the Act, and we do not have any evidence to suggest there was confusion resulting from this difference, we do not find a risk of increased confusion from reverting to these differing approaches. Further, we have few species with overlapping jurisdiction to cause such potential confusion.

Exceptions for Federally Recognized Tribes

Comment 25: Commenters requested including Tribes in the exception to aid or salvage endangered species at 50 CFR 17.21(c)(3) and 17.61(c)(2).

Response: The Act provides no authority to extend existing exceptions for endangered species to additional entities not listed in the statute.

Comment 26: Many commenters supported the proposal to add federally recognized Tribes to the list of entities that are excepted from the take prohibition for aiding a sick, injured, or orphaned specimen or disposing/salvaging of a dead specimen of a threatened species. Several commenters said this change was a recognition that Tribes are independent governmental sovereigns with inherent powers to make and enforce laws, administer justice, and manage and control their natural resources, similar to States, and that adding them to this exception recognizes their sovereignty and the government-to-government relationship with Tribes. A commenter stated that Tribal wildlife managers need clear authority under the Act to take these actions without having to first get a permit. The commenter noted that Tribal land includes remote locations, some without Service or State offices; as a result, finding someone to get to the scene in a timely manner to euthanize a suffering animal can be very difficult. They add that in some locations, even waiting for a reply from Service law enforcement can sometimes take hours, a long time in a suffering animal's life; therefore, giving Tribes the ability to make these on-the-ground decisions is a good step forward. Another commenter said that, while they anticipated ''take'' under these permissions would be nominal and not negatively impact the overall population or health of a species, any new permissions should not extend beyond what is already granted to Federal and State agencies.

Response: This revision to the threatened species regulations is in recognition of the sovereignty of Tribes and the merit of allowing any employee or agent of a federally recognized Tribe, who is designated by the Tribe for such purpose, to be able to aid injured or diseased wildlife or plants or dispose of dead individuals without a permit. Consistent with various Executive orders, Secretary's orders, and memoranda, and in recognition of the governmental authority of Tribes and their expertise in managing natural resources on Tribal lands, we are now

extending this exception to Tribes to the same extent and in the same manner that it is given to the Service, NMFS, Federal land management agencies, and State conservation agencies. We agree that time is of the essence in aiding or salvaging threatened species and that this revision will give Tribes the ability to make on-the-ground decisions regarding threatened species in remote areas of their lands. This will have a beneficial impact on the conservation of threatened species without any negative impact on their health. We, therefore, find that extending this exception is necessary and advisable to provide for the conservation of the species.

Comment 27: Several commenters suggested that the Service should conduct thorough and meaningful consultation with federally recognized Tribes on how adding the exception to take for aiding or salvaging threatened species affects them and should continue to engage Tribes about how best to craft these regulations. Another commenter recommended requiring a cooperative agreement for Tribes to aid or salvage threatened species.

Response: The longstanding policy of the Department of the Interior (DOI) has been to carry out responsibilities under the Act and other statutes in harmony with the Federal trust responsibility to Tribes and to strive to ensure that Tribes do not bear a disproportionate burden for the conservation of listed species (DOI Secretary's Order 3206 (June 5, 1997)). Additionally, the commitments described in recent Executive orders and memoranda (including Tribal Consultation and Strengthening Nation-to-Nation Relationships (86 FR 7491; January 29, 2021), Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (86 FR 7009; January 25, 2021), and Advancing Equity, Justice, and Opportunity for Asian Americans, Native Hawaiians, and Pacific Islanders (86 FR 29675; June 3, 2021)) include ensuring that Federal agencies conduct regular, meaningful, and robust consultation with Tribal officials in the development of Federal research, policies, and decisions, especially decisions that may affect Tribal Nations and the people they represent. In light of the unique relationship between Tribes and the United States, we will continue to engage in meaningful government-to-government consultation with Tribes on the conservation of listed species. We are extending this exception to Tribes because Tribes have the authority and expertise to manage natural resources on their own lands, and we do not see it as appropriate to require them to obtain a permit or to develop a cooperative agreement with the Service for aiding injured or diseased threatened species of wildlife or plants or dispose of dead individuals.

Comment 28: We received comments supporting and opposing extending to Tribes the exception to take of threatened species for conservation activities. As with the exception for aiding an ailing specimen or disposing or salvaging of a dead specimen, many commenters thought that the proposed change recognized the sovereignty of Tribes, their extensive wildlife expertise and experience, and the importance of bringing Indigenous Knowledge to species conservation. Commenters noted the Service has the authority to modify, renew, or terminate a cooperative agreement with the States and that applying this same mechanism to federally recognized Tribes would be consistent with current implementation practices of the Act. One commenter stated that, while anticipated ''take'' under these permissions should be nominal and not negatively impact the overall population or health of a species, any new permissions should not extend beyond what is already granted to Federal and State agencies. Many commenters stated that the Service should work closely with Tribes to define an appropriate mechanism and agreement for this change. Other commenters questioned whether the Act applies to Tribal lands and whether this exception was needed given that Tribes are sovereign entities. One commenter added that many Tribes have species and habitat protections and restrictions codified into their laws and regulations that are enforced by other divisions or departments of the Tribe or by the Tribe itself. One commenter noted that the exception would merely trade out one requirement (obtaining a take permit with Service permission) with another (obtaining a cooperative agreement with Service permission) and that the Service should be making it easier for Tribes to undertake conservation activities, not harder. Another commenter stated that the requirement that a cooperative agreement must be initiated, negotiated, and signed conflicts with the sovereign nature of federally recognized Tribes and their jurisdiction and authority to manage their own on-reservation resources, including federally listed species.

Response: In light of comments received and further consideration, we are not at this time moving forward with an additional provision excepting from the prohibitions any take by federally recognized Tribes in the course of conducting conservation activities. Instead, we intend to take the time to coordinate and collaborate with Tribes to craft language that best meets their needs. As stated elsewhere in this document, we are finalizing this rule as we proposed, including authorizing federally recognized Tribes to aid or salvage threatened species without a permit under the Act.

Comment 29: A commenter expressed concern about our reference to Indigenous Knowledge in the preamble of the June 22, 2023, proposed rule and suggested that this directly and illegally conflicts with the unambiguous language of section 4(b)(1)(A) of the Act, which states that the Secretary shall make determinations required by section 4(a)(1) of the Act solely on the basis of the best scientific and commercial data available after conducting a review of the status of the species and after taking into account those efforts, if any, being made by any State or foreign nation, or any political subdivision of a State or foreign nation, to protect such species, whether by predator control, protection of habitat and food supply, or other conservation practices, within any area under its jurisdiction, or on the high seas. They also stated that the Secretary has no legal or constitutional authority to revise the Act and implement such revisions through regulations.

Response: We disagree that consideration of Indigenous Knowledge conflicts with section 4(b)(1)(A) of the Act. The statute does not define the phrase ''best scientific and commercial data available'' in section 4(a)(1), and this regulation merely applies the Act rather than revising it in any way. We undertake this rulemaking in accordance with the delegated authority to the Service to implement the Act, and this rulemaking falls within the broad discretion that section 4(d) of the Act provides the Secretary to put into place protections deemed necessary and advisable for the conservation of threatened species. We provide references to multiple memoranda, Executive orders, and Secretarial orders in the preamble to the June 22, 2023, proposed rule (88 FR 40742 at 40746) that describe the rationale for our inclusion of federally recognized Tribes as entities authorized to aid or salvage threatened species. Further, under the White House Council on Environmental Quality and the White House Office of Science and Technology Policy Guidance for Federal Departments and Agencies on Indigenous Knowledge (November 30, 2022), Indigenous Knowledge is a valid form of evidence for inclusion in Federal policy, research, and decision making, including decision making under the Act.

Comment 30: A commenter said that along with extending certain section 4(d) exceptions or other opportunities to federally recognized Tribes, the Service must explicitly recognize, and commit to fulfill, its obligations to conduct regular, meaningful, and robust consultation with Alaska Native Corporations (ANCs) and, in consultation with ANCs, it should consider whether it would be appropriate to extend to ANCs the exceptions that it is considering providing to federally recognized Tribes.

Response: A number of recent memoranda and Executive orders describe the commitment of the U.S. Government to strengthening the relationship between the Federal Government and Tribal Nations and to advance equity for Indigenous Peoples, including Native Americans, Alaska Natives, Native Hawaiians, and Indigenous Peoples of the U.S. Territories. These include the Memorandum on Tribal Consultation and Strengthening Nation-to-Nation Relationships (86 FR 7491; January 29, 2021); Executive Order 13985: Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (86 FR 7009; January 25, 2021); Executive Order 14031: Advancing Equity, Justice, and Opportunity for Asian Americans, Native Hawaiians, and Pacific Islanders (86 FR 29675; June 3, 2021); the Memorandum on Indigenous Traditional Ecological Knowledge and Federal Decision Making (November 15, 2021); and the Memorandum on Uniform Standards for Tribal Consultation (87 FR 74479; December 5, 2022). The commitments described in these recent Executive orders and memoranda include ensuring that Federal agencies conduct regular, meaningful, and robust consultation with Tribal officials in the development of Federal research, policies, and decisions, especially decisions that may affect Tribal Nations and the people they represent. Our obligation to have a government-to-government relationship with federally recognized Tribes is paramount and, in addition to Executive orders and policies on the government-to-government relationship, is covered by Secretaries' Orders (S.O.) 3206 and 3225. While S.O. 3225 discusses ''Alaska Natives'' and ''other Native organizations,'' its purpose is to protect subsistence rights and ways of life, and states that the Departments of Commerce and the Interior will seek to enter into cooperative agreements for the conservation of specific species, such as marine mammals and migratory birds, and the co-management of subsistence uses with these organizations.

In the Consolidated Appropriations Act of 2004 (Pub. L. 108–199, Div. H, sec. 161), Congress required that the Director of the Office of Management and Budget (and, subsequently, all Federal agencies) consult with Alaska Native Corporations on the same basis as Indian Tribes under Executive Order 13175. Consistent with this obligation, the Service will consult on Federal decisions that have a substantial, direct effect on an ANC. This obligation to consult does not extend beyond the E.O. 13175 context. Extending protections to specific employees of Federal, State, and Tribal governments who are designated to handle threatened species for the stated purposes is within the Service's authority, but the fact that E.O. 13175 states that we must consult with ANCs does not mean that it is appropriate to extend the same protections to employees of for-profit corporations. If this is a service that an ANC wants their employees to provide to rural communities, then the Service can assist them with the process to be granted a permit to do so.

Required Determinations

Comment 31: Several commenters requested, and asserted reasons for, additional economic analyses for this rulemaking. One commenter suggested that the Service must undertake a detailed economic analysis under Executive Order (E.O.) 12866 and related E.O.s because the Service characterized the rulemaking as a ''significant regulatory action,'' and that we must include an economic analysis as specified in Office of Management and Budget (OMB) Circular A–4. Other commenters suggested that the requirement in section 4(d) of the Act for the Service to issue protective regulations that are ''necessary and advisable'' for the species' conservation means that the Service is required to undertake an economic analysis or cost/benefit analysis pursuant to the Supreme Court's decision in *Michigan* v. *Environmental Protection Agency (Michigan* v. *EPA),* 576 U.S. 743, 769 (2015).

Commenters also offered ways in which the Service could undertake such an analysis for this rulemaking. One such commenter stated the Service has experienced periods of time both with and without a ''blanket rule'' and could analyze the differences between those periods to estimate how reauthorizing the ''blanket rules'' would affect the Service's implementation of section 4(d), the costs it imposes on States and private landowners, and the likelihood that species recover. Another commenter stated that the Service had studied the resource impacts of switching to species-specific ''take'' prohibitions as part of our 2019 4(d) rule, including using data on resource burdens from the Service's previous species-specific 4(d) rules to estimate the potential increased resource burden associated with a switch from a ''blanket rule'' approach to an approach tailored to specific species; these commenters suggested that we could undertake a similar study for these regulations.

Response: After considering the authorities that commenters cite as requiring the Service to undertake a detailed economic analysis for this rulemaking, we have concluded that none of them establishes such a requirement. First, OMB did designate the June 22, 2023, proposed rule (88 FR 40742) as ''significant'' pursuant to section 3(f) of E.O. 12866 but did not characterize the rulemaking specifically as significant under section 3(f)(1). Therefore, we are not required to provide a detailed economic analysis of the costs and benefits of the rule. See E.O. 12866 sec. 6(a)(3)(B), (C).

We retain the conviction that—to ensure we can defend listing decisions by demonstrating, as Congress has required, that we make the decisions ''solely on the basis of the best scientific and commercial data available''—we must maintain separation between listing decisions and any information not related to whether the species meets the definition of an endangered or a threatened species. To maintain this separation, the Service does not compile or describe the costs or benefits of 4(d) rules that are promulgated concurrently with listing the species.

With respect to the ''necessary and advisable'' language in section 4(d), we have concluded that the phrase does not create a *de facto* requirement for the Service to analyze the costs and benefits of all 4(d) rules. First, as we discuss in the Necessary and Advisable Determination section, the Service has not interpreted the ''necessary and advisable'' phrase to apply to the ''blanket rules'' because it does not apply to regulations that extend section 9 prohibitions to threatened species. Second, as we explain in the following paragraphs below about the *Michigan* v. *EPA* decision, the standard that the Act sets out for evaluating ''necessary and advisable''—that the protective regulations must be necessary and advisable *to provide for the conservation of the* species—does not incorporate any requirement to

undertake an economic analysis or other cost/benefit analysis.

We have analyzed the Supreme Court decision in *Michigan* v. *EPA* and have concluded that it does not require the Service to consider the costs of reinstating the ''blanket rules'' because the Court's ruling there was specific to the statutory language at issue in that case, and section 4(d) of the Act lacks the statutory attributes that were pivotal to the Court's decision. In *Michigan* v. *EPA,* the Supreme Court interpreted a provision of the Clean Air Act (CAA) that ''directs the [EPA] to regulate power plants if it 'finds such regulation is appropriate and necessary.' '' 576 U.S. at 751 (quoting 42 U.S.C. 7412(n)(1)(A)). The Court disapproved of EPA's interpretation that, under that statute, cost was irrelevant, and held that EPA ''must consider cost . . . before deciding whether regulation is appropriate and necessary.'' *Id.* at 759. Although commenters assert that the relevant CAA standard (''appropriate and necessary'') is similar to the standard in section 4(d) of the Act (''necessary and advisable''), the language in the two statutes differs in significant ways, confirming that the Supreme Court's ruling in that case does not apply in the context of 4(d) rules. The Court's decision in *Michigan* v. *EPA* revolved around three central attributes in the CAA language—in particular, that: (1) the statute was mandating a decision about whether or not to regulate; (2) the standard that the statute prescribed for determining whether to regulate was whether it was necessary and ''appropriate,'' and the statute did not include additional considerations that might narrow that consideration; and (3) related provisions within the statute expressly factored in cost. See *id.* at 752–55. The standard in section 4(d) of the Act shares none of those attributes: (1) section 4(d) does not involve a decision on whether or not to regulate or protect threatened species—instead, under the Act, the Service must issue protective regulations for threatened species and must determine what provisions to include in those regulations [16 U.S.C. 1533(d)]; (2) the standard in section 4(d) of the Act does not contain the term ''appropriate,'' which the Court focused on as ''the classic broad and all-encompassing term that naturally and traditionally includes consideration of all the relevant factors,'' *id.* at 752 (quotation omitted); and (3) the Act's requirement to issue such regulations as the Secretary ''deems necessary and advisable to provide for the conservation of such species'' is not surrounded by other provisions identifying cost as a factor—rather, with the limited exceptions of recovery planning under section 4(f) and potential exclusions from critical habitat under section 4(b)(2), there are no references at all to costs in section 4 of the Act.

With respect to comments about approaches to undertaking an economic analysis, we disagree with the assertions that we have data either prior to or after 2019 that would allow for their suggested approaches. In addition, the Service did not estimate any resource burden differences associated with the 2019 4(d) rule in the document entitled ''Effects Data for the Revision of the Regulations on Prohibitions That Apply to Threatened Wildlife and Plants,'' and we do not have the data to conduct such analyses. Instead, we forecasted the number of potential species listed as threatened species and the increased number of species-specific rules that would be required due to the removal of the ''blanket rule'' options.

Between the time that the 2019 4(d) rule went into effect in September 2019 and early January 2024, we listed or reclassified 44 threatened species (33 wildlife and 11 plant species) and finalized associated species-specific 4(d) rules for each of those species. During that time, there were no newly listed threatened species for which time elapsed between listing and putting in place protective regulations because we finalized species-specific rules concurrently with each final classification action. Since all of the 4(d) rules promulgated after September 2019 were species-specific 4(d) rules, this data would not shed light on the potential costs or benefits of reinstating the ''blanket rules.''

Comment 32: Several commenters believed the Service's findings under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*) and consideration of responsibilities under Executive Order (E.O.) 13132 (Federalism) and E.O. 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) were insufficient or incorrect. Commenters suggested that protecting threatened species in the future through the use of ''blanket rules'' would result in much greater impacts than protecting threatened species in the future through the use of species-specific 4(d) rules. The commenters also disagreed with our finding for E.O. 12630 (Takings) that the proposed rule would not have significant takings implications and that a takings implication assessment is not warranted. They urged us to conduct additional assessments before finalizing the rule.

Response: Regarding all required determinations for the rulemaking, the primary change that this final rule makes is simply to put a regulatory framework in place for future application. In the future, for each threatened species, we will apply regulatory protections for that threatened species that are necessary and advisable—either by promulgating a species-specific 4(d) rule or by applying a ''blanket rule'' to that species.

Similarly, the changes that this rule makes to currently listed species will not result in significant differences in outcomes. As discussed elsewhere in this document, the substantive changes to protections for currently listed threatened species are limited to: (1) allowing Tribes to aid/salvage dead, injured, or diseased individuals without a section 10 permit, which reduces regulatory burden for Tribes; and (2) incorporating the existing provisions of the 1988 amendments to the Act that prohibit the malicious damage or destruction of threatened plants on an area under Federal jurisdiction or the removal, cutting, digging up, or damage or destruction of such plants on any other area in knowing violation of any State law or regulation or in the course of any violation of a State criminal trespass law. These minor changes for threatened species of plants will not substantially affect anyone.

Regarding the RFA and E.O. 13211, because the changes are primarily instructive regulations, this rulemaking does not directly affect small entities or any other entities and is unlikely to cause any adverse effects on energy supply, distribution, or use (including a shortfall in supply, price increases, and increased use of foreign supplies).

Regarding E.O. 13132, ''Federalism,'' that E.O. includes federalism implications from regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. This rulemaking has no such federalism implications. The Service is the only entity that is directly affected by this rule, as we are the only entity that will apply these regulations to protect threatened species, and the regulatory changes to endangered species result in no material changes. In addition, as stated below under Required Determinations in *Federalism (E.O. 13132),* both the ''blanket rules'' and species-specific 4(d) rules include explicit exceptions for States that have

entered into cooperative agreements with the Service to conduct conservation programs for threatened species. This rule will further the goals of conservation and recovery of endangered species and threatened species, as the Service is mandated to do. Further, the Act requires that for any threatened species the Service issue protective regulations that are necessary and advisable to provide for their conservation. This is a duty that cannot be delegated to States. While serving to advance the conservation purposes of the Act, this rule will not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Regarding E.O. 12630, as discussed in the June 22, 2023, proposed rule and below under Required Determinations, this rulemaking will not directly affect private property, nor will it cause a physical or regulatory taking. It will not result in a physical taking because it will not effectively compel a property owner to suffer a physical invasion of property. Further, the rulemaking will not result in a regulatory taking because it will not deny all economically beneficial or productive use of the land or aquatic resources and it will substantially advance a legitimate government interest (conservation and recovery of endangered species and threatened species) and will not present a barrier to all reasonable and expected beneficial use of private property.

Comment 33: Some commenters asserted that the Service needs to prepare an environmental assessment or environmental impact statement pursuant to National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) for these revisions to the regulations and that this rulemaking action should not be categorically excluded. Specifically, they suggest that we need to take a hard look at the foreseeable impacts of the regulatory changes, along with a reasonable range of alternatives. One commenter requested that we make any NEPA documentation available prior to issuing a final rule.

Response: We have complied with NEPA by determining that the rule is covered by a categorical exclusion found at 43 CFR 46.210(i). We explained this determination in an environmental action statement (EAS) that is posted in the docket for this rule. As explained in the EAS, this rulemaking primarily provides the framework for protections to threatened species but does not apply this framework to any species; it is not until we list a species as threatened and decide whether to issue a species-specific 4(d) rule or protect the species with a ''blanket rule'' that this framework applies to that species. Another aspect of this rulemaking is to make edits to the regulatory protections for endangered species to bring those protections into conformity with the 1988 amendments to the statute. In addition, the rulemaking makes two substantive changes for currently listed threatened species that were protected under prior versions of the ''blanket rules'' or under species-specific 4(d) rules that refer to any of the sections we are revising. First, we add federally recognized Tribes to the entities authorized to aid, salvage, or dispose of threatened species. Second, as a result of updating our endangered plant regulations at 50 CFR 17.61(c)(1) to match amendments to the Act that Congress enacted in 1988, the implementing regulations now also make clear that threatened plants protected under the previous ''blanket rule'' are protected from being maliciously damaged or destroyed on areas under Federal jurisdiction; or being removed, cut, dug up, or damaged or destroyed on any other area in knowing violation of any law or regulation of any State or in the course of any violation of a State criminal trespass law.

In light of this information, the framework and minor regulatory changes in this rulemaking will not have any significant impacts on the human environment. Further, when the Service proposes any future species-specific 4(d) rules that are not concurrent with the final listing rule, the proposed action will be subject to the NEPA process at that time.

Comment 34: Some commenters asserted the need to complete intra-Service consultation pursuant to section 7 of the Act on the issuance of the final regulations.

Response: We address this below under *Endangered Species Act* in Required Determinations.

Required Determinations

Regulatory Planning and Review—Executive Orders 12866, 13563, and 14094

Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) will review all significant rules. OIRA has determined that this rule is significant. Executive Order 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. Executive Order 14094 amends E.O. 12866 and reaffirms the principles of E.O. 12866 and E.O 13563 and states that regulatory analysis should facilitate agency efforts to develop regulations that serve the public interest, advance statutory objectives, and be consistent with E.O. 12866 and E.O. 13563. Regulatory analysis, as practicable and appropriate, shall recognize distributive impacts and equity, to the extent permitted by law. We have developed this rule in a manner consistent with these requirements.

We are revising portions of the implementing regulations at 50 CFR part 17. The preamble to this rule details how the regulatory changes we are adopting will improve the implementation of the Act. The revisions to 50 CFR 17.31 and 17.71 reinstate the general application of the ''blanket rule'' option for protecting newly listed threatened wildlife and plant species, respectively, pursuant to section 4(d) of the Act. The regulations retain the continued option to promulgate species-specific 4(d) rules.

When we removed the ''blanket rule'' options in 2019, we compiled certain historical data regarding the numbers of threatened wildlife and plant species that the Service had listed, along with the number of species-specific 4(d) rules that we had adopted, each year between 1997 and 2018 (the analysis timeframe) in an effort to describe for OMB and the public the potential effects of those regulations (on *https://www.regulations.gov/,* see Supporting Document No. FWS–HQ–ES–2018–0007–69539 of Docket No. FWS–HQ–ES–2018–0007). For those species listed prior to September 26, 2019, we also had the option to issue species-specific rules, which we did approximately 25 percent of the time. Between that rule's effective date in September 2019 and early January 2024, we listed or reclassified 44 threatened species (33 wildlife and 11 plant species) and finalized associated species-specific rules for each of those species. During that time, there were no newly listed threatened species for which time elapsed between listing and putting in place protective regulations because we finalized species-specific rules concurrently with each final classification action.

With reinstatement of the ''blanket rules,'' we anticipate that in some cases we will continue to propose and finalize species-specific 4(d) rules that are designed to meet the specific conservation needs of particular species.

However, in other situations, we may find that the standard suite of prohibitions and exceptions for threatened species in the ''blanket rule'' is appropriate because that is what is necessary and advisable to provide for the protection of those species. We can anticipate only that, because the ''blanket rule'' option had been available for the more than 40 years between early in the administration of the Act and the effective date of the 2019 4(d) rule (September 26, 2019), we do not anticipate any material effects to the process or outcomes as a result of reinstatement of the ''blanket rules.'' However, because protections for threatened species are so highly fact-specific, it is not possible to specify future benefits or costs stemming from the revisions.

The updates we are finalizing to the endangered plant regulations at 50 CFR 17.61(c)(1) to match amendments to the Act that Congress enacted in 1988 (ESA section 9(a)(2)(B), 16 U.S.C. 1538(a)(2)(B); Pub. L. 100–478 (October 7, 1988)) and other minor edits, also referred to as technical corrections (*e.g.,* in 50 CFR 17.8, 17.21, 17.31, 17.61, and 17.71), will improve readability, increase consistency among sections, provide alignment with the Act, and correct other inaccuracies. These minor edits will not materially change the protections provided to threatened or endangered species or their effects on any potentially regulated entities.

We are also revising 50 CFR 17.31 and 17.71 to extend to federally recognized Tribes the exceptions to prohibitions for threatened species that the regulations currently provide to the Service and other Federal and State agencies to aid, salvage, or dispose of threatened species. These revisions reduce the regulatory burden or potential legal risks on Tribes associated with conducting these activities. There may also be cost savings for the Service for reduced permit application processing. We cannot specify the extent to which there may be reduced costs to Tribes associated with permit applications or risk of law enforcement action, as we cannot predict which species may be listed as threatened species, and of those species, which may occur in areas in which federally recognized Tribes may conduct these actions.

The revisions further the effectiveness of the Service's program to carry out the statutory mandates for conserving threatened species. There are no identifiable quantifiable effects from the rule. There may be reduced administrative costs for federally recognized Tribes or the Service associated with a potential reduction in permitting. We do not anticipate any material effects such that the rule would have an annual effect that would reach or exceed $200 million or would 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, territorial, or Tribal governments or communities.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996; 5 U.S.C. 601 *et seq.*), whenever a Federal agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare, and make available for public comment, a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency, or that person's designee, certifies that the rule will not have a significant economic impact on a substantial number of small entities. SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities. We certified at the proposed rule stage that the proposed rule would not have a significant economic impact on a substantial number of small entities (88 FR 40742, June 22, 2023). Nothing in this final rule changes the basis for that conclusion, and we received no information that changes the factual basis of this certification.

This rulemaking revises the Service's regulations protecting endangered and threatened species under the Act. The changes in this rule are instructive regulations and do not directly affect small entities. The Service is the only entity directly affected by this rule, as we are the only entity that applies these regulations to protect threatened species, and the regulatory changes to endangered species result in no material changes. External entities, including any small businesses, small organizations, or small governments, are not directly regulated by this rule and thus will not experience any direct economic impacts from this rule.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*):

(a) On the basis of information presented under *Regulatory Flexibility Act* above, this rule will not ''significantly or uniquely'' affect small governments. We have determined and certify pursuant to the Unfunded Mandates Reform Act, that this rule will not impose a cost of $100 million or more in any given year on local or State governments or private entities. A small government agency plan is not required. As explained above, small governments will not be affected because the rule will not place additional requirements on any city, county, or other local municipalities.

(b) This rule will not produce a Federal mandate on State, local, or Tribal governments or the private sector of $100 million or greater in any year; that is, this rule is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act. This rule will impose no obligations on State, local, or Tribal governments.

Takings (E.O. 12630)

In accordance with E.O. 12630, this rule will not have significant takings implications. This rule will not directly affect private property, nor will it cause a physical or regulatory taking. It will not result in a physical taking because it will not effectively compel a property owner to suffer a physical invasion of property. Further, the rule will not result in a regulatory taking because it will not deny all economically beneficial or productive use of the land or aquatic resources, and it will substantially advance a legitimate government interest (conservation and recovery of endangered species and threatened species) and will not present a barrier to all reasonable and expected beneficial use of private property.

Federalism (E.O. 13132)

In accordance with E.O. 13132, we have considered whether this rule will have significant federalism effects and have determined that a federalism summary impact statement is not required. This rule pertains only to the Service's protective regulations for endangered species and threatened species promulgated under the Act and will not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. The Service is the only entity that is directly affected by this rule, as we are the only entity that will apply these regulations to protect threatened species, and the regulatory changes to endangered species result in no material changes. In

addition, both the ''blanket rules'' and species-specific 4(d) rules include explicit exceptions for States that have entered into cooperative agreements with the Service to conduct conservation programs for threatened species, recognizing the important role that States play in the conservation of listed species.

Civil Justice Reform (E.O. 12988)

This rule does not unduly burden the judicial system and meets the applicable standards provided in sections 3(a) and 3(b)(2) of E.O. 12988. This rule revises the Service's regulations for protecting species pursuant to the Act.

Government-to-Government Relationship With Tribes

In accordance with E.O. 13175, ''Consultation and Coordination with Indian Tribal Governments,'' and the Department of the Interior's manual at 512 DM 2, we have considered possible effects of this rule on federally recognized Indian Tribes and Alaska Native Corporations. We held three informational webinars for federally recognized Tribes in January 2023, before the June 22, 2023, proposed rule published, to provide a general overview of, and information on how to provide input on, a series of rulemakings related to implementation of the Act that the Service and NMFS were developing, including the June 22, 2023, proposed rule to revise our regulations at 50 CFR part 17. In July 2023, we also held six informational webinars after the proposed rule published, to provide additional information to interested parties, including Tribes, regarding the proposed regulations. More than 500 attendees, including representatives from federally recognized Tribes and Alaska Native Corporations, participated in these sessions, and we addressed questions from the participants as part of the sessions. We received written comments from Tribal organizations; however, we did not receive any requests for coordination or government-to-government consultation from any federally recognized Tribes. We received one request to consult with Alaska Native Corporations.

These regulations will 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. This rule is general in nature and does not directly affect any specific Tribal lands, treaty rights, or Tribal trust resources. Therefore, we conclude that this rule does not have Tribal implications under section 1(a) of E.O. 13175. Thus, formal government-to-government consultation is not required by E.O. 13175 and related DOI policies. This rule revises regulations for protecting endangered and threatened species pursuant to the Act. The only provision in these regulations that could appear to have an effect on Tribes is the exception to aid, salvage, or dispose of threatened species. However, the inclusion of this exception does not require any Tribe to do anything or change their management practices. Further, we are not changing the relationship between the Service and Tribes. The provision simply provides a new mechanism for compliance with the Act. These regulations will 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.

We will continue to collaborate with Tribes and Alaska Native Corporations on issues related to federally listed species and their habitats and will work with them as we implement the provisions of the Act. See Secretaries' Order 3206 (''American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act,'' June 5, 1997) and Secretaries' Order 3225 (''Endangered Species Act and Subsistence Uses in Alaska (Supplement to Secretarial Order 3206),'' January 19, 2001).

Paperwork Reduction Act

This rule does not contain any new collection of information that requires approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). OMB has previously approved the information collection requirements associated with permitting and reporting requirements and assigned OMB Control Number 1018–0094 (expires 01/31/2024). 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.

National Environmental Policy Act

We have analyzed this rule in accordance with the criteria of the NEPA (42 U.S.C. 4321 *et seq.*), the Department of the Interior regulations on Implementation of the National Environmental Policy Act (43 CFR 46.10 through 46.450), and the Department of the Interior Manual (516 DM 8). On June 3, 2023, NEPA was amended by the Fiscal Responsibility Act (Pub. L. 118–5). These amendments codified a procedure for determining the appropriate level of NEPA review. Under these statutory standards, which generally reflect the same standards previously applicable by regulation, an environmental impact statement is only required for an action that has a reasonably foreseeable significant effect on the quality of the human environment. An environmental assessment is not required for actions that do not have a reasonably foreseeable significant effect on the quality of the human environment, or have effects of unknown significance if the agency finds, *inter alia,* that the action is excluded pursuant to one of the agency's categorical exclusions. We have determined that a detailed statement under NEPA is not required because the rule is covered by a categorical exclusion. We find that the categorical exclusion found at 43 CFR 46.210(i) applies to these regulation changes. At 43 CFR 46.210(i), the Department of the Interior has found that the following category of actions would not individually or cumulatively have a significant effect on the human environment and are, therefore, categorically excluded from the requirement for completion of an environmental assessment or environmental impact statement: Policies, directives, regulations, and guidelines: that are of an administrative, financial, legal, technical, or procedural nature; or whose environmental effects are too broad, speculative, or conjectural to lend themselves to meaningful analysis and will later be subject to the NEPA process, either collectively or case-by-case. We have also considered whether any of the extraordinary circumstances described in 43 CFR 46.215 is present, and we did not identify any extraordinary circumstances that apply to this rulemaking. When the Service proposes any 4(d) rules that are not concurrent with the listing rule for the respective species, the proposed action will be subject to the NEPA process at that time.

Endangered Species Act

As discussed in our June 22, 2023, proposed rule (88 FR 40742 at 40750), in developing aspects of this rule, we are acting in our unique statutory role as administrator of the Act and are engaged in a legal exercise of interpreting the standards of the Act. Our promulgation of interpretive rules that govern our implementation of the Act is not an action that is in itself subject to the Act's provisions, including section 7(a)(2). For this reason, we have a historical practice of

issuing our general implementing regulations under the Act without undertaking section 7 consultation. Given the plain language, structure, and purposes of the Act, we find that Congress never intended to place a consultation obligation on our promulgation of implementing regulations under the Act.

As part of this rulemaking, we are revising implementing regulations to interpret the statute or to align the regulations with changes Congress has made to the statute. These revisions include updating endangered plant regulations at 50 CFR 17.61(c)(1) to match amendments to the Act that Congress enacted in 1988. This revision does not alter any protections for endangered plants. We also make corrections or clarifications to regulations for both endangered species and threatened species that result in no substantive change in protection for either currently listed species or species listed in the future. For example, we make minor changes to clarify, without changing the scope or intent of, the existing regulations in several locations (*e.g.,* 50 CFR 17.21, 17.31, 17.32), as well as technical corrections such as revising the use of the phrase ''special rule'' to ''species-specific rule'' in several locations (*e.g.,* 50 CFR 17.8, 17.40). We make these revisions for the purpose of improving readability, increasing consistency among sections, and correcting other inaccuracies. These aspects, if proposed on their own, would not result in our undertaking section 7 consultation.

In addition to discussing in the proposed rule that aspects of the proposal fell within our unique statutory role as administrator of the Act, we also recognized that we may need to conduct a section 7 analysis on some aspects of the rulemaking. After further consideration, we find that, for one aspect of this rulemaking, application of section 7(a)(2) is appropriate because our role is more akin to our role as an ''action agency'' principally implementing provisions of the Act, rather than defining the Act's standards as an administrator of the Act. This aspect is reinstating the ''blanket rule'' options at 50 CFR 17.31(a) and 17.71(a), which will automatically apply to every future threatened species unless we issue a species-specific 4(d) rule. Reinstating the ''blanket rules'' determines the protections that are necessary and advisable for species that are listed as threatened species in the future without a species-specific 4(d) rule.

Because this aspect of the rulemaking is more akin to our role as an ''action agency'' principally implementing provisions of the Act, we fulfilled our section 7 responsibilities to determine whether the overall action of reinstating and updating the ''blanket rules'' ''may affect'' listed species or critical habitat. We found there will be no effects to listed species or critical habitat, as we have no information identifying any generalized environmental changes that would not occur but for this rule and are reasonably certain to occur. See our section 7 determination at *https://www.regulations.gov* for additional information.

Energy Supply, Distribution or Use (E.O. 13211)

Executive Order 13211 requires agencies to prepare statements of energy effects when undertaking certain actions. The revised regulations are not expected to affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action, and no statement of energy effects is required.

Authority

We issue this rule under the authority of the Endangered Species Act, as amended (16 U.S.C. 1531 *et seq.*).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Plants, Reporting and recordkeeping requirements, Transportation, Wildlife.

Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

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

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

Subpart A—Introduction and General Provisions

■ 2. Amend § 17.3 by revising the definition for ''Convention'' to read as follows:

§ 17.3 Definitions.

* * * * *

Convention means the Convention on International Trade in Endangered Species of Wild Fauna and Flora, TIAS 8249 (see part 23 of this chapter).

* * * * *

■ 3. Amend § 17.8 by revising paragraph (a) and the introductory text of paragraph (b) to read as follows:

§ 17.8 Import exemption for threatened, CITES Appendix-II wildlife.

(a) Except as provided in a species-specific rule in §§ 17.40 through 17.48 or in paragraph (b) of this section, all provisions of §§ 17.31 and 17.32 apply to any specimen of a threatened species of wildlife that is listed in Appendix II of the Convention.

(b) Except as provided in a species-specific rule in §§ 17.40 through 17.48, any live or dead specimen of a fish and wildlife species listed as threatened under this part may be imported without a threatened species permit under § 17.32 provided all of the following conditions are met:

* * * * *

Subpart C—Endangered Wildlife

■ 4. Amend § 17.21 by revising paragraphs (c) and (d) to read as follows:

§ 17.21 Prohibitions.

* * * * *

(c) *Take.* (1) It is unlawful to take endangered wildlife within the United States, within the territorial sea of the United States, or upon the high seas. The high seas include all waters seaward of the territorial sea of the United States, except waters officially recognized by the United States as the territorial sea of another country, under international law.

(2) Notwithstanding paragraph (c)(1) of this section, any person may take endangered wildlife in defense of their own life or the lives of others.

(3) Notwithstanding paragraph (c)(1) of this section, any employee or agent of the Service, any other Federal land management agency, the National Marine Fisheries Service, or a State conservation agency, who is designated by their agency for such purposes, may, when acting in the course of their official duties, take endangered wildlife without a permit if such action is necessary to:

(i) Aid a sick, injured, or orphaned specimen; or

(ii) Dispose of a dead specimen; or

(iii) Salvage a dead specimen that may be useful for scientific study; or

(iv) Remove specimens that constitute a demonstrable but nonimmediate threat to human safety, provided that the taking is done in a humane manner; the taking may involve killing or injuring only if it has not been reasonably possible to eliminate such threat by live-capturing and releasing the specimen unharmed in an appropriate area.

(4) Any taking under paragraphs (c)(2) and (3) of this section must be reported in writing to the Office of Law Enforcement via contact methods listed at *https://www.fws.gov,* within 5 calendar days. The specimen may only be retained, disposed of, or salvaged under directions from the Office of Law Enforcement.

(5) Notwithstanding paragraph (c)(1) of this section, any qualified employee or agent of a State conservation agency that is a party to a cooperative agreement with the Service in accordance with section 6(c) of the Act, who is designated by their agency for such purposes, may, when acting in the course of their official duties, take those endangered species that are covered by an approved cooperative agreement for conservation programs in accordance with the cooperative agreement, provided that such taking is not reasonably anticipated to result in:

(i) The death or permanent disabling of the specimen;

(ii) The removal of the specimen from the State where the taking occurred;

(iii) The introduction of the specimen so taken, or of any progeny derived from such a specimen, into an area beyond the historical range of the species; or

(iv) The holding of the specimen in captivity for a period of more than 45 consecutive days.

(6) Notwithstanding paragraph (c)(1) of this section, any person acting under a valid migratory bird rehabilitation permit issued pursuant to § 21.76 of this subchapter may take endangered migratory birds without an endangered species permit if such action is necessary to aid a sick, injured, or orphaned endangered migratory bird, provided the permittee is adhering to the conditions of the migratory bird rehabilitation permit.

(7) Notwithstanding paragraph (c)(1) of this section and consistent with § 21.76(a) of this subchapter:

(i) Any person who finds a sick, injured, or orphaned endangered migratory bird may, without a permit, take and possess the bird in order to immediately transport it to a permitted rehabilitator; and

(ii) Persons exempt from the permit requirements of § 21.12(b)(2) and (c) of this subchapter may take sick and injured endangered migratory birds without an endangered species permit in performing the activities authorized under § 21.12(b)(2) and (c) of this subchapter.

(d) *Possession and other acts with unlawfully taken wildlife.* (1) It is unlawful to possess, sell, deliver, carry, transport, or ship, by any means whatsoever, any endangered wildlife that was taken in violation of paragraph (c) of this section.

Example 1 to paragraph (d)(1). A person captures a whooping crane, an endangered species, in Texas and gives it to a second person, who puts it in a closed van and drives 30 miles to another location in Texas. The second person then gives the whooping crane to a third person, who is apprehended with the bird in his possession. All three people have violated the law: the first by illegally taking the whooping crane; the second by transporting an illegally taken whooping crane; and the third by possessing an illegally taken whooping crane.

(2) Notwithstanding paragraph (d)(1) of this section, Federal and State law enforcement officers may possess, deliver, carry, transport, or ship any endangered wildlife taken in violation of the Act as necessary in performing their official duties.

(3) Notwithstanding paragraph (d)(1) of this section, any person acting under a valid migratory bird rehabilitation permit issued pursuant to § 21.76 of this subchapter may possess and transport endangered migratory birds without an endangered species permit when such action is necessary to aid a sick, injured, or orphaned endangered migratory bird, provided the permittee is adhering to the conditions of those permits.

(4) Notwithstanding paragraph (d)(1) of this section, and consistent with § 21.76(a) of this subchapter, persons exempt from the permit requirements of § 21.12(b)(2) and (c) of this subchapter may possess and transport sick and injured endangered migratory bird species without an endangered species permit in performing the activities authorized under § 21.12(b)(2) and (c) of this subchapter.

* * * * *

Subpart D—Threatened Wildlife

■ 5. Revise § 17.31 to read as follows:

§ 17.31 Prohibitions.

(a) Except as provided in §§ 17.4 through 17.8, or in a permit issued pursuant to § 17.32, the provisions of paragraph (b) of this section and all of the provisions of § 17.21 (for endangered species of wildlife), except § 17.21(c)(3) and (5), apply to threatened species of wildlife, unless the Secretary has promulgated species-specific provisions (see paragraph (c) of this section).

(b)(1) Notwithstanding § 17.21(c)(1), and unless otherwise specified, any employee or agent of the Service, any other Federal land management agency, the National Marine Fisheries Service, a State conservation agency, or a federally recognized Tribe, who is designated by their agency or Tribe for such purposes, may, when acting in the course of their official duties, take threatened wildlife without a permit if such action is necessary to:

(i) Aid a sick, injured, or orphaned specimen; or

(ii) Dispose of a dead specimen; or

(iii) Salvage a dead specimen that may be useful for scientific study; or

(iv) Remove specimens that constitute a demonstrable but nonimmediate threat to human safety, provided that the taking is done in a humane manner; the taking may involve killing or injuring only if it has not been reasonably possible to eliminate such threat by live-capturing and releasing the specimen unharmed, in an appropriate area.

(2) Any taking under paragraph (b)(1) of this section must be reported in writing to the Office of Law Enforcement, via contact methods listed at *https://www.fws.gov,* within 5 calendar days. The specimen may only be retained, disposed of, or salvaged under directions from the Office of Law Enforcement.

(3) Notwithstanding § 17.21(c)(1), and unless otherwise specified, any employee or agent of the Service, of the National Marine Fisheries Service, or of a State conservation agency that is operating a conservation program pursuant to the terms of an approved cooperative agreement with the Service that covers the threatened species of wildlife in accordance with section 6(c) of the Act, who is designated by their agency for such purposes, may, when acting in the course of their official duties, take those species.

(c) For threatened species of wildlife that have a species-specific rule in §§ 17.40 through 17.48, the provisions of paragraph (b) of this section and § 17.32 apply unless otherwise specified, and the species-specific rule will contain all of the prohibitions and any additional exceptions that apply to that species.

■ 6. Amend § 17.32 by revising the introductory text to read as follows:

§ 17.32 Permits—general.

Upon receipt of a complete application, the Director may issue a permit for any activity otherwise prohibited with regard to threatened wildlife. The permit shall be governed by the provisions of this section unless a species-specific rule applicable to the wildlife and set forth in §§ 17.40 through 17.48 provides otherwise. A permit issued under this section must be for one of the following purposes: scientific purposes, or the enhancement of propagation or survival, or economic hardship, or zoological exhibition, or educational purposes, or incidental

taking, or special purposes consistent with the purposes of the Act. Such a permit may authorize a single transaction, a series of transactions, or a number of activities over a specific period of time.

* * * * *

■ 7. Amend § 17.40 by revising the section heading to read as follows:

§ 17.40 Species-specific rules—mammals.

* * * * *

■ 8. Amend § 17.41 by revising the section heading to read as follows:

§ 17.41 Species-specific rules—birds.

* * * * *

■ 9. Amend § 17.42 by revising the section heading to read as follows:

§ 17.42 Species-specific rules—reptiles.

* * * * *

■ 10. Amend § 17.43 by revising the section heading to read as follows:

§ 17.43 Species-specific rules—amphibians.

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■ 11. Amend § 17.44 by revising the section heading to read as follows:

§ 17.44 Species-specific rules—fishes.

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■ 12. Amend § 17.45 by revising the section heading to read as follows:

§ 17.45 Species-specific rules—snails and clams.

* * * * *

■ 13. Amend § 17.46 by revising the section heading to read as follows:

§ 17.46 Species-specific rules—crustaceans.

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■ 14. Amend § 17.47 by revising the section heading to read as follows:

§ 17.47 Species-specific rules—insects.

* * * * *

§ 17.48 [Removed and Reserved]

■ 15. Remove and reserve § 17.48.

Subpart F—Endangered Plants

■ 16. Amend § 17.61 by revising paragraphs (a), (b), and (c) to read as follows:

§ 17.61 Prohibitions.

(a) *General prohibitions.* Except as provided in a permit issued pursuant to § 17.62 or § 17.63, it is unlawful for any person subject to the jurisdiction of the United States to commit, to attempt to commit, to solicit another to commit, or to cause to be committed, any of the acts described in paragraphs (b) through (e) of this section in regard to any endangered plant.

(b) *Import or export.* It is unlawful to import or to export any endangered plant. Any shipment in transit through the United States is an importation and an exportation, whether or not it has entered the country for customs purposes.

(c) *Remove and reduce to possession.* (1) It is unlawful to remove and reduce to possession any endangered plant from an area under Federal jurisdiction; maliciously damage or destroy the species on any such area; or remove, cut, dig up, or damage or destroy the species on any other area in knowing violation of any law or regulation of any State or in the course of any violation of a State criminal trespass law.

(2) Notwithstanding paragraph (c)(1) of this section, any employee or agent of the Service, any other Federal land management agency, or a State conservation agency who is designated by their agency for such purposes may, when acting in the course of official duties, remove and reduce to possession endangered plants from areas under Federal jurisdiction without a permit if such action is necessary to:

(i) Care for a damaged or diseased specimen;

(ii) Dispose of a dead specimen; or

(iii) Salvage a dead specimen that may be useful for scientific study.

(3) Any removal and reduction to possession pursuant to paragraph (c)(2) of this section must be reported in writing to the Office of Law Enforcement, via contact methods listed at *https://www.fws.gov,* within 5 calendar days. The specimen may only be retained, disposed of, or salvaged under directions from the Office of Law Enforcement.

(4) Notwithstanding paragraph (c)(1) of this section, any qualified employee or agent of a State conservation agency that is a party to a cooperative agreement with the Service in accordance with section 6(c) of the Act, who is designated by their agency for such purposes, may, when acting in the course of official duties, remove and reduce to possession from areas under Federal jurisdiction those endangered plants that are covered by an approved cooperative agreement for conservation programs in accordance with the cooperative agreement, provided that such removal is not reasonably anticipated to result in:

(i) The death or permanent damage of the specimens;

(ii) The removal of the specimen from the State where the removal occurred; or

(iii) The introduction of the specimen so removed, or of any propagules derived from such a specimen, into an area beyond the historical range of the species.

* * * * *

Subpart G—Threatened Plants

■ 17. Revise § 17.71 to read as follows:

§ 17.71 Prohibitions.

(a) Except as provided in a permit issued pursuant to § 17.72, the provisions of paragraph (b) of this section and all of the provisions of § 17.61, except § 17.61(c)(2) through (4), apply to threatened species of plants, unless the Secretary has promulgated species-specific provisions (see paragraph (c) of this section), with the following exception: Seeds of cultivated specimens of species treated as threatened are exempt from all the provisions of § 17.61, provided that a statement that the seeds are of ''cultivated origin'' accompanies the seeds or their container during the course of any activity otherwise subject to the regulations in this subpart.

(b)(1) Notwithstanding § 17.61(c)(1) and unless otherwise specified, any employee or agent of the Service, any other Federal land management agency, federally recognized Tribe, or a State conservation agency, who is designated by their agency or Tribe for such purposes, may, when acting in the course of official duties, remove and reduce to possession threatened plants from areas under Federal jurisdiction without a permit if such action is necessary to:

(i) Care for a damaged or diseased specimen;

(ii) Dispose of a dead specimen; or

(iii) Salvage a dead specimen that may be useful for scientific study.

(2) Any removal and reduction to possession pursuant to paragraph (b)(1) of this section must be reported in writing to the Office of Law Enforcement, via contact methods listed at *https://www.fws.gov,* within 5 calendar days. The specimen may only be retained, disposed of, or salvaged under directions from the Office of Law Enforcement.

(3) Notwithstanding § 17.61(c)(1) and unless otherwise specified, any employee or agent of the Service or of a State conservation agency that is operating a conservation program pursuant to the terms of an approved cooperative agreement with the Service that covers the threatened species of plants in accordance with section 6(c) of the Act, who is designated by their agency for such purposes, may, when acting in the course of official duties, remove and reduce to possession from

areas under Federal jurisdiction those species.

(c) For threatened species of plants that have a species-specific rule in §§ 17.73 through 17.78, the provisions of paragraph (b) of this section and § 17.72 apply unless otherwise specified, and the species-specific rule will contain all the prohibitions and any additional exceptions that apply to that species.

■ 18. Amend § 17.72 by revising the introductory text to read as follows:

§ 17.72 Permits—general.

Upon receipt of a complete application, the Director may issue a permit authorizing any activity otherwise prohibited with regard to threatened plants. The permit shall be governed by the provisions of this section unless a species-specific rule applicable to the plant and set forth in §§ 17.73 through 17.78 provides otherwise. A permit issued under this section must be for one of the following: scientific purposes, the enhancement of the propagation or survival of threatened species, economic hardship, botanical or horticultural exhibition, educational purposes, or other activities consistent with the purposes and policy of the Act. Such a permit may authorize a single transaction, a series of transactions, or a number of activities over a specified period of time.

* * * * *

■ 19. Amend § 17.73 by revising the section heading to read as follows:

§ 17.73 Species-specific rules—flowering plants.

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■ 20. Amend § 17.74 by revising the section heading to read as follows:

§ 17.74 Species-specific rules—conifers and cycads.

* * * * *

Shannon Estenoz,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2024–06901 Filed 4–2–24; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 240401–0094; RTID 0648–XD513]

Magnuson-Stevens Act Provisions; Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Allocation of 2024 Northeast Multispecies Annual Catch Entitlements

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

ACTION: Final rule.

SUMMARY: This final rule allocates Northeast multispecies annual catch entitlements to approved groundfish sectors and permit banks for fishing year 2024 based on 2024 annual catch limits set in Framework Adjustment 65 to the Northeast Multispecies Fishery Management Plan or default specifications. This action is intended to allow limited access permit holders to continue to operate sectors, as authorized under the Northeast Multispecies Fishery Management Plan.

DATES: Northeast multispecies annual catch entitlements for sectors are effective May 1, 2024, through April 30, 2025. Default catch limits are effective May 1, 2024, through October 31, 2024, or until the final rule for Framework Adjustment (Framework) 66 is implemented, if that final rule is implemented prior to October 31, 2024. If Framework 66 is not implemented on or before October 31, 2024, sectors would be prohibited from fishing in the stock areas of stocks with expired default specifications beginning November 1, 2024.

ADDRESSES: Copies of each sector's operations plan and contracts from fishing years 2023–2024; the Sector Operations Plan, Contract, and Environmental Assessment Requirements guidance document for fishing years 2023–2024, as well as the programmatic environmental assessment for sector operations in fishing years 2015 to 2020 and a supplemental information report analyzing sector operations for fishing years 2023 and 2024; and other supporting documents are available from the NMFS Greater Atlantic Regional Fisheries Office (GARFO). Copies of supporting documents are available from: Claire Fitz-Gerald at *Claire.Fitz-Gerald@noaa.gov.* These documents are also accessible via the GARFO website. These documents and the **Federal Register** documents referenced in this rule are also accessible via the internet at: *https://www.fisheries.noaa.gov/management-plan/northeast-multispecies-management-plan.*

FOR FURTHER INFORMATION CONTACT: Claire Fitz-Gerald, Fishery Policy Analyst, (978) 281–9255.

SUPPLEMENTARY INFORMATION:

Background

The Northeast Multispecies Fishery Management Plan (FMP) defines a sector as ''a group of persons holding limited access Northeast multispecies permits who have voluntarily entered into a contract and agree to certain fishing restrictions for a specified period of time, and which has been granted a [total allowable catch] TAC(s) [*sic*] in order to achieve objectives consistent with applicable FMP goals and objectives.'' (50 CFR 648.2 ''Sector'') A sector must be comprised of at least three Northeast multispecies permits issued to at least three different persons, none of whom have any common ownership interest in the permits, vessels, or businesses associated with the permits issued to the other two or more persons in that sector. As long as at least three persons issued a Northeast multispecies permit meet these requirements, permit owners may have common ownership interests in other permits, vessels, or businesses associated with such permits. Sectors are self-selecting, meaning participation is voluntary, and each sector can choose its members.

The Northeast multispecies sector management system includes an annual allocation of available catch for a portion of the Northeast multispecies stocks to each approved sector. These annual sector allocations are known as annual catch entitlements (ACE) and are based on the collective fishing history of the permits held by a sector's members. Sectors may receive allocations of large-mesh Northeast multispecies stocks with the exception of Atlantic halibut, windowpane flounder, Atlantic wolffish, and ocean pout, which are non-allocated species managed under separate effort controls. ACEs are portions of a stock's annual catch limit (ACL) available to commercial Northeast multispecies vessels. A sector determines how to harvest its ACE.

Because sectors elect to receive an allocation under a quota-based system, the FMP grants sector vessels several universal exemptions from the FMP's effort controls. These universal

exemptions apply to: Trip limits on allocated stocks; portions of the Gulf of Maine (GOM) Cod Protection Closures; Northeast multispecies days-at-sea (DAS) restrictions; the requirement to use a 6.5-inch (16.5-centimeter (cm)) mesh codend when fishing with selective gear on Georges Bank (GB); and the minimum codend mesh size restrictions for trawl gear when fishing in compliance with the provisions of the Redfish Exemption Program. The FMP allows the Council to add universal exemptions using the framework adjustment procedure. Sectors may request additional exemptions annually as part of their sector operations plans to increase flexibility and fishing opportunities. The FMP prohibits sectors from requesting exemptions from permitting restrictions, gear restrictions designed to minimize habitat impacts, and most reporting requirements.

In addition to the sectors, there are several state-operated permit banks that each receive an allocation based on the fishing history of permits they hold. The final rule implementing Amendment 17 to the FMP (77 FR 16942; March 23, 2012) allowed a state-operated permit bank to receive an allocation without needing to comply with sector administrative and procedural requirements. Instead, permit banks are required to submit a list of permits to NMFS, as specified in the permit bank's Memorandum of Agreement between NMFS and the state, to determine the ACE allocated to the permit bank. These allocations may be leased to fishermen enrolled in sectors. State-operated permit banks are no longer approved through the sector approval process, but current state-operated permit banks contribute to the total allocation under the sector system.

NMFS previously approved 15 sectors to operate in fishing years 2023 and 2024, and also approved 18 requested exemptions for sectors (88 FR 26502; May 1, 2023). Copies of the operations plans and contracts from fishing years 2023–2024, the Sector Operations Plan, Contract, and the Environmental Assessment Requirements guidance document for fishing years 2023–2024, the programmatic environmental assessment (PEA), and other supporting documents are available at: *https://www.fisheries.noaa.gov/species/northeast-multispecies* and from NMFS (see **ADDRESSES**). NMFS previously prepared a supplemental information report analyzing sector operations for fishing years 2023 and 2024, which determined that the potential impacts to the fishery from the measures described above fall within the scope of the PEA developed in support of sector operations for fishing years 2015 through 2020. This report is available at *https://www.fisheries.noaa.gov/new-england-mid-atlantic/commercial-fishing/fishing-year-2023-sectors* and from NMFS (see **ADDRESSES**). This final rule allocates 2024 ACE to the approved sectors and permit banks based on preliminary fishing year 2024 rosters and the fishing year 2024 catch limits set in Framework 65 (88 FR 56527; August 18, 2023) to the FMP or default specifications.

Operations Plan Submissions and Changes

Annually, NMFS solicits operations plan submissions for consideration and approval. Prior to the 2023 fishing year, NMFS received 15 sector operations plans, all of which were approved for fishing years 2023 and 2024 (88 FR 26502; May 1, 2023). These approved sectors are not required to resubmit operations plans for 2024. NMFS did not receive any new operations plans for approval for fishing year 2024. In addition, sectors may request changes to approved operations plans as needed to implement changes to their operations. NMFS did not receive any submissions for substantive changes to approved operations plans for fishing year 2024.

Catch Limits for Fishing Year 2024

Previously Established Catch Limits

Last year, Framework 65 (88 FR 56527; August 18, 2023) set catch limits for 16 groundfish stocks: GB haddock, GOM haddock, Southern New England/Mid-Atlantic (SNE/MA) yellowtail flounder, Cape Cod (CC)/GOM yellowtail flounder, American plaice, witch flounder, GB winter flounder, GOM winter flounder, SNE/MA winter flounder, pollock, ocean pout, Atlantic halibut, and Atlantic wolffish for fishing years 2023–2025; GB cod and GB yellowtail flounder for fishing years 2023–2024; and white hake for fishing year 2023. Framework 66 will set catch limits for 8 groundfish stocks: Acadian redfish, northern windowpane flounder, and southern windowpane flounder for fishing years 2024–2026; and GB cod, GB haddock, GOM haddock, GB yellowtail flounder, and white hake for fishing years 2024–2025. However, Framework 66 may not be in place by May 1, 2024, the start of the fishing year. To prevent disruption to the groundfish fishery while Framework 66 is finalized, this final rule announces default catch limits that will be in effect for Acadian redfish, northern windowpane flounder, southern windowpane flounder, and white hake until October 31, 2024, or until Framework 66 is finalized and goes into effect.

As a result, the sector and common pool allocations in this rule are based on the 2024 catch limits set in Framework 65 or default catch limits that will be effective on May 1, 2024, and preliminary 2024 fishing year rosters (table 1). If NMFS approves Framework 66, the 2024 catch limits for 8 (out of 20) groundfish stocks announced in this rule will be changed and published when Framework 66 measures become effective.

Default Catch Limits

This rule announces default fishing year 2024 catch limits for Acadian redfish, northern windowpane flounder, southern windowpane flounder, and white hake (table 1). These stocks do not already have a catch limit in place for fishing year 2024. The groundfish regulations implement default catch limits for any stock for which final specifications are not in place by the beginning of the fishing year on May 1. The FMP's default specifications provision in the regulations at 50 CFR 648.90(a)(3) sets catch limits at 75 percent of the previous year's (2023) catch limits, except in instances where the default catch limit would exceed the Council's recommendation for the final specifications. The default catch limits are effective from May 1 through October 31, or until the final rule for Framework 66 is implemented if that final rule is implemented prior to October 31. These default specifications are set out in the regulations to minimize impacts on the fishery that would occur if no catch limits are specified. If Framework 66 is not implemented on or before October 31, all fishing for these stocks would be prohibited beginning November 1. The prohibition would remain in effect for the remainder of the fishing year, unless and until the catch limits in Framework 66 are implemented. This includes redfish, white hake, northern windowpane flounder, and southern windowpane flounder stocks.

TABLE 1—NORTHEAST MULTISPECIES CATCH LIMITS FOR 2024

Stock	Total U.S. ABC (mt)	Commercial groundfish sub-ACL (mt)
GB Cod *	519	374.9
GOM Cod *	551	278.1
GB Haddock *	11,638	10,834.9
GOM Haddock *	2,038	1,209.2
GB Yellowtail Flounder *	106	84.3
SNE/MA Yellowtail Flounder *	40	33.4
CC/GOM Yellowtail Flounder *	992	876.4
American Plaice *	5,520	5,191.6
Witch Flounder *	1,256	1,145.5
GB Winter Flounder *	1,549	1,487.5
GOM Winter Flounder *	804	607.2
SNE/MA Winter Flounder *	627	440.8
Redfish #	7,475	7,101.5
White Hake #	1,384	1,369.2
Pollock	13,940	12,183.6
N Windowpane Flounder #	120	78.7
S Windowpane Flounder #	288	33.5
Ocean Pout *	87	49
Atlantic Halibut *	86	64.1
Atlantic Wolffish *	93	86.5

* These catch limits are based on Framework 65.
# These catch limits are based on default specifications and will be replaced when the final rule for Framework 66 becomes effective, if approved. If Framework 66 is not implemented on or before October 31, all fishing for these stocks would be prohibited beginning November 1.

Sector Allocations for Fishing Year 2024

This rule allocates ACE to sectors and permit banks based on the preliminary fishing year 2024 sector rosters and the 2024 catch limits established in Framework 65 or default specifications. Any permits that change ownership after the enrollment deadline established by the Regional Administrator (March 13, 2024) retain the ability to join a sector through April 30, 2024. All permit holders who have joined a sector for fishing year 2024 have until April 30, 2024, to withdraw and instead elect to fish in the common pool, although sectors may specify a more restrictive withdrawal date for their members. As a result, the total permits enrolled in sectors for fishing year 2024 could change from the preliminary rosters, although such changes are expected to be minimal based on past fishing years.

NMFS calculates the sector's allocation for each stock by summing its members' potential sector contributions (PSC) for a stock and then multiplying that total percentage by the available commercial sub-ACL for that stock. Table 2 shows the preliminary projected total PSC for each sector, by stock, for fishing year 2024 based on preliminary 2024 rosters. Tables 3 and 4 show estimates of the preliminary allocations that each sector will be allocated, in pounds and metric tons, respectively, for fishing year 2024, based on their preliminary fishing year 2024 rosters and the 2024 catch limits established in Framework 65 or default specifications. As soon as practicable after the start of the 2024 fishing year, final allocations to the nearest pound are provided directly to each sector based on their final May 1 rosters. NMFS uses these final allocations, along with later adjustments, including ACE transfers, reductions for overages, or increases for carryover from fishing year 2023, to monitor sector catch. The common pool collectively may harvest an amount of a particular stock equal to the common pool sub-ACL, which is a portion of the commercial groundfish quota for that stock. The common pool sub-ACLs are also included tables 3 and 4. The common pool sub-ACLs are managed separately from sectors and do not contribute to available ACE for leasing or harvest by sector vessels. The preliminary common pool sub-ACLs are included in tables 2 through 4 for comparison.

Instead of assigning separate PSCs for the eastern GB cod or eastern GB haddock, a PSC is assigned to each permit for the GB cod stock and GB haddock stock. Each sector's GB cod and GB haddock allocations are then divided into an eastern ACE and a western ACE, based on each sector's percentage of the GB cod and GB haddock ACLs. For example, if a sector is allocated 4 percent of the GB cod ACL, the sector is allocated 4 percent of the commercial eastern GB cod TAC as its eastern GB cod. The eastern GB haddock allocations are determined in the same way. These amounts are then subtracted from the sector's overall GB cod and haddock allocations to determine its western GB cod and haddock ACEs. A sector may only harvest its eastern GB cod and haddock ACEs in the Eastern U.S./Canada Area. A sector may also ''convert,'' or transfer, its eastern GB cod or haddock allocation into western GB allocation and harvest that converted ACE outside the eastern GB geographic area.

Each sector is required to ensure that it does not exceed its ACE during the fishing year. Sector vessels are required to retain all legal-sized allocated Northeast multispecies stocks, unless a sector is granted an exemption allowing its member vessels to discard legal-sized unmarketable fish at sea. Catch (defined as landings and discards) of all allocated Northeast multispecies stocks by a sector's vessels counts against the sector's allocation. Groundfish catch from a sector trip targeting non-groundfish species will be deducted from the sector's ACE because these are groundfish trips using gear capable of catching groundfish. Catch from a non-sector trip in an exempted fishery does not count against a sector's allocation and is assigned to a separate ACL sub-component to account for any groundfish bycatch that occurs in non-groundfish fisheries.

NMFS expects final 2023 catch information for sectors to be ready in summer 2024. To reduce or eliminate

any fishing year 2023 overages, NMFS will allow sectors to trade fishing year 2023 ACE for 2 weeks after completion of the year-end catch accounting. If necessary, NMFS will reduce any sector's fishing year 2024 allocation to account for a remaining overage in fishing year 2023. Each year, NMFS notifies the Council and sector managers of this deadline in writing and announces its final ACE determination at: *https://www.fisheries.noaa.gov/species/northeast-multispecies.*

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Table 2 -- Cumulative PSC (Percentage) Each Sector Would Receive by Stock for Fishing Year 2024*

Sector Name	MRI Count	GB Cod	GOM Cod	GB Haddock	GOM Haddock	GB Yellowtail Flounder	SNE/MA Yellowtail Flounder	CC/GOM Yellowtail Flounder	Plaice	Witch Flounder	GB Winter Flounder	GOM Winter Flounder	SNE/MA Winter Flounder	Redfish	White Hake	Pollock
Fixed Gear Sector	59	10.66368130	0.69697957	1.73925106	0.19342970	1.33811259	0.20776918	1.80040167	0.69211258	1.41865619	2.25552402	2.03553546	0.96475271	0.55322185	0.98718417	2.69363866
Maine Coast Community Sector	106	2.14346576	15.77574417	3.28033123	12.14315523	1.94946572	2.52115190	6.24764686	15.57467423	12.30874340	0.80738762	7.86986961	2.23258492	9.19242287	13.81106273	12.67065727
Maine Permit Bank	11	0.13439158	1.16146439	0.04453277	1.12519137	0.01387770	0.03207071	0.31964833	1.16764302	0.72914170	0.00021875	0.42733162	0.01820600	0.82280520	1.65671908	1.69628627
Mooncusser Sector	48	12.02921920	6.25777157	3.84823447	3.69074677	1.23201147	0.86256446	3.02845586	0.86052723	1.81794552	0.95245393	2.85202511	2.48746222	4.75054253	10.67782404	10.53593863
NEFS 2	134	9.49872888	27.03357997	14.42403106	25.27417443	3.91163986	6.84782846	27.91222741	15.67097593	20.79218577	4.45167800	27.91508790	5.66793541	21.97944839	13.34211300	18.13675481
NEFS 4	58	8.63064256	11.18021805	6.05566788	8.86146971	2.17847227	2.28497979	6.42213790	9.43836833	8.82303299	0.69996269	7.42431329	1.03538340	6.69552217	8.27302876	7.26648727
NEFS 5	18	0.45848210	0.32875539	0.45599711	0.11135826	0.74730041	15.06499951	0.92544848	0.29012444	0.46535873	0.19884758	0.84381463	9.55163414	0.01340476	0.06758295	0.06684655
NEFS 6	3	0.53277963	0.16897341	0.55629310	0.15125674	0.06623359	0.00032970	0.02492228	0.88199052	0.47903664	0.08026315	0.07106409	0.01437459	1.11265001	0.52914348	0.31850611
NEFS 8	107	32.14429894	6.47349254	39.69437836	19.01532607	41.10369352	17.89837197	18.46919615	21.30707462	20.59414302	56.89277908	6.45104508	39.87083431	26.35138368	19.18519781	18.73824650
NEFS 10	23	0.36099982	1.80011246	0.11620637	1.06678057	0.00106541	0.56787338	3.22717458	0.44936350	0.95408609	0.01076846	7.06053027	0.54528800	0.01774808	0.05484715	0.08997485
NEFS 11	42	0.39886389	11.36750608	0.03379870	2.73739463	0.00147257	0.01232212	2.28957044	1.51568258	1.54445775	0.00310767	2.00546790	0.02573992	1.86957788	4.01717963	8.77006607
NEFS 12	25	0.66695944	3.70211898	0.15518034	1.33202724	0.00051982	0.03715834	9.30680020	1.54946832	1.79775784	0.00058497	12.24691996	0.33391380	0.54739034	0.89356742	1.39219765
NEFS 13	65	11.00132100	0.56476011	16.41446401	0.88555368	34.45892048	23.09421386	7.31716540	7.59921581	7.70632237	19.12551115	2.08860917	16.34008330	1.80768009	1.33448880	1.35854205
New Hampshire Permit Bank	4	0.00082696	1.15165725	0.00003421	0.03236683	0.00002041	0.00001803	0.02192453	0.02856511	0.00617882	0.00000326	0.06080509	0.00003694	0.01942367	0.08147906	0.11143280
Sustainable Harvest Sector 1	59	6.59488586	6.97935052	8.49027525	16.80493455	6.25856384	5.46705969	4.82490089	16.51623947	13.41249257	10.92899272	4.02657897	5.54519351	18.46133885	20.22470442	11.80101981
Sustainable Harvest Sector 2	20	1.75601730	1.68695288	2.35874044	4.19777672	0.93533973	1.71793597	2.56396440	2.81484093	2.78750859	0.63465289	3.06112792	2.50774026	4.79387649	3.44070357	3.23580284
Sustainable Harvest Sector 3	3	0.08038283	0.18792499	0.00389341	0.25359846	0.00000000	0.48368689	0.80290989	0.90262401	0.81756929	0.00000000	0.58666734	0.78545860	0.03544103	0.43984416	0.11493299
Common Pool	479	2.90405294	3.48263768	2.32869024	2.12345904	5.80329061	22.89966603	4.49550472	2.74050939	3.54538270	2.95726407	12.97320661	12.07337797	0.97612211	0.98332978	1.00266889
All Sectors	785	97.10	96.52	97.67	97.88	94.20	77.10	95.50	97.26	96.45	97.04	87.03	87.93	99.02	99.02	99.00

* The data in this table are based on preliminary sector rosters for fishing year 2024 and may change based on final sector enrollment.

Table 3 -- Estimated ACE (in 1,000 pounds), by Stock, for Each Sector for Fishing Year 2024*#

Sector Name	GB Cod East	GB Cod West	GOM Cod	GB Haddock East	GB Haddock West	GOM Haddock	GB Yellowtail Flounder	SNE/MA Yellowtail Flounder	CC/GOM Yellowtail Flounder	Plaice	Witch Flounder	GB Winter Flounder	GOM Winter Flounder	SNE/MA Winter Flounder	Redfish	White Hake	Pollock
FGS	32	56	4	58	357	5	2	0	35	79	36	74	27	9	87	30	724
MCCS	6	11	97	110	674	324	4	2	121	1,783	311	26	105	22	1,439	417	3,403
MPB	0	1	7	1	9	30	0	0	6	134	18	0	6	0	129	50	456
Mooncusser	36	64	38	129	790	98	2	1	59	98	46	31	38	24	744	322	2,830
NEFS 2	28	50	166	483	2,962	674	7	5	539	1,794	525	146	374	55	3,441	403	4,872
NEFS 4	26	46	69	203	1,244	236	4	2	124	1,080	223	23	99	10	1,048	250	1,952
NEFS 5	1	2	2	15	94	3	1	11	18	33	12	7	11	93	2	2	18
NEFS 6	2	3	1	19	114	4	0	0	0	101	12	3	1	0	174	16	86
NEFS 8	96	170	40	1,330	8,152	507	76	13	357	2,439	520	1,866	86	387	4,126	579	5,033
NEFS 10	1	2	11	4	24	28	0	0	62	51	24	0	95	5	3	2	24
NEFS 11	1	2	70	1	7	73	0	0	44	173	39	0	27	0	293	121	2,356
NEFS 12	2	4	23	5	32	36	0	0	180	177	45	0	164	3	86	27	374
NEFS 13	33	58	3	550	3,371	24	64	17	141	870	195	627	28	159	283	40	365
NHPB	0	0	7	0	0	1	0	0	0	3	0	0	1	0	3	2	30
SHS 1	20	35	43	285	1,744	448	12	4	93	1,890	339	358	54	54	2,890	611	3,170
SHS 2	5	9	10	79	484	112	2	1	50	322	70	21	41	24	751	104	869
SHS 3	0	0	1	0	1	7	0	0	16	103	21	0	8	8	6	13	31
Common Pool	9	15	21	78	478	57	11	17	87	314	90	97	174	117	153	28	269
Sector Total	289	514	592	3,273	20,058	2,609	175	57	1,845	11,132	2,436	3,182	1,165	854	15,503	2,991	26,591

* The data in this table are based on preliminary fishing year 2024 sector rosters, and represent the preliminary total allocations to each sector. Final allocations will be determined using final fishing year 2024 rosters. The data also includes ACEs based on default specifications that may change if Framework 66 is approved.

Numbers are rounded to the nearest thousand pounds. In some cases, this table shows an allocation of 0, but that sector may be allocated a small amount of that stock in tens or hundreds pounds.

Table 4 -- Estimated ACE (in metric tons), by Stock, for Each Sector for Fishing Year 2024*#

Sector Name	GB Cod East	GB Cod West	GOM Cod	GB Haddock East	GB Haddock West	GOM Haddock	GB Yellowtail Flounder	SNE/MA Yellowtail Flounder	CC/GOM Yellowtail Flounder	Plaice	Witch Flounder	GB Winter Flounder	GOM Winter Flounder	SNE/MA Winter Flounder	Redfish	White Hake	Pollock
FGS	14	26	2	26	162	2	1	0	16	36	16	34	12	4	39	14	328
MCCS	3	5	44	50	306	147	2	1	55	809	141	12	48	10	653	189	1,544
MPB	0	0	3	1	4	14	0	0	3	61	8	0	3	0	58	23	207
Mooncusser	16	29	17	58	358	45	1	0	27	45	21	14	17	11.0	337	146	1,284
NEFS 2	13	23	75	219	1,344	306	3	2	245	814	238	66	170	25	1,561	183	2,210
NEFS 4	12	21	31	92	564	107	2	1	56	490	101	10	45	5	475	113	885
NEFS 5	1	1	1	7	42	1	1	5	8	15	5	3	5	42	1	1	8
NEFS 6	1	1	0	8	52	2	0	0	0	46	5	1	0	0	79	7	39
NEFS 8	43	77	18	603	3,697	230	35	6	162	1,106	236	846	39	176	1,871	263	2,283
NEFS 10	0	1	5	2	11	13	0	0	28	23	11	0	43	2	1	1	11
NEFS 11	1	1	32	1	3	33	0	0	20	79	18	0	12	0	133	55	1,069
NEFS 12	1	2	10	2	14	16	0	0	82	80	21	0	74	1	39	12	170
NEFS 13	15	26	2	249	1,529	11	29	8	64	395	88	284	13	72	128	18	166
NHPB	0	0	3	0	0	0	0	0	0	1	0	0	0	0	1	1	14
SHS 1	9	16	19	129	791	203	5	2	42	857	154	163	24	24	1,311	277	1,438
SHS 2	2	4	5	36	220	51	1	1	22	146	32	9	19	11	340	47	394
SHS 3	0	0	1	0	0	3	0	0	7	47	9	0	4	3	3	6	14
Common Pool	4	7	10	35	217	26	5	8	39	142	41	44	79	53	69	13	122
Sector Total	131	233	268	1,485	9,098	1,184	79	26	837	5,049	1,105	1,444	528	388	7,032	1,356	12,061

* The data in this table are based on preliminary fishing year 2024 sector rosters, and represent the preliminary total allocations to each sector. Final allocations will be determined using final fishing year 2024 rosters. The data also includes ACEs based on default specifications that may change if Framework 66 is approved.

Numbers are rounded to the nearest metric ton, but allocations are made in pounds. In some cases, this table shows a sector allocation of 0 metric tons, but that sector may be allocated a small amount of that stock in pounds.

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Sector Operations Plans and Contracts

Fifteen sectors are approved to operate in fishing year 2024 (88 FR 26502; May 1, 2023). NMFS did not receive any new sector operations plans or substantive updates to existing operations plans for fishing year 2024. All 15 approved sectors were active in fishing year 2023. Approved operations plans contain the rules under which each sector will fish, and also provide the legal contract that binds each member to the sector for the length of the sector's operations plan. Each sector's operations plan, and each sector's members, must comply with the regulations governing sectors, found at 50 CFR 648.87. In addition, each sector must conduct fishing activities as detailed in its approved operations plan.

Participating vessels are required to comply with all pertinent Federal fishing regulations, except as specifically exempted in the letter of authorization (LOA) issued by the Regional Administrator, which details any approved sector exemptions from the regulations. If, during the fishing year, a sector requests an exemption that NMFS already granted, or proposes a change to administrative provisions, NMFS may amend that sector's operations plan. Should any such amendments require modifications to LOAs, NMFS will include these changes in updated LOAs and provide them to the appropriate sectors.

NMFS may revoke exemptions in-season if: it determines that the exemption jeopardizes management measures, FMP objectives, or rebuilding efforts; the exemption results in unforeseen negative impacts on other managed fish stocks, habitat, or protected resources; the exemption causes enforcement concerns; catch from trips using the exemption cannot be adequately monitored; or a sector is not meeting certain administrative or operational requirements. If it becomes necessary to revoke an exemption, NMFS will do so through a process consistent with the existing regulations or in a separate rulemaking action, as appropriate.

Sector Monitoring Programs

Sectors are responsible for developing and implementing a monitoring program that must be: (1) approved by NMFS as both sufficient to monitor catch, discards, and use of ACE; and (2) consistent with the FMP's goals and objectives for the sector monitoring program.

For fishing year 2024, sector vessels may choose to use at-sea monitoring (ASM) or the audit model electronic monitoring (EM) program to meet monitoring requirements, provided that the sector has a corresponding monitoring program approved as part of its operations plan. At the January 2024 meeting of the New England Fishery Management Council, NMFS announced the suspension of the maximized retention EM (MREM) program for fishing year 2024 due to the exceedingly high administrative cost per vessel of managing the program given its extraordinarily low participation rate. NMFS intends to revisit this decision for fishing year 2025 and may decide to operate MREM in 2025. On February 20, 2024, NMFS announced a preliminary ASM coverage target of 100 percent of all sector groundfish trips for the 2024 fishing year. The preliminary coverage level was announced to facilitate preparations by industry members and monitoring companies ahead of the 2024 fishing year. In order to develop the 2024 ASM spend plan, NMFS is currently evaluating whether the preliminary coverage level target can be met given the level of 2024 appropriations funding for reimbursing sectors for the cost of monitoring. The final ASM coverage level will be announced when Congress approves the 2024 ASM spend plan. Vessels that choose to use ASM to meet monitoring requirements will be assigned monitors based on the target coverage level set for all sector groundfish trips. Vessels that choose to use EM to meet monitoring coverage requirements must use cameras and adhere to catch handling protocols as described in their vessel monitoring plans for all groundfish trips.

Only a subset of the submitted trips will be selected for review to monitor groundfish discards for catch accounting. A subset of the selected EM trips will also undergo review by NMFS to monitor the third-party service provider's performance. The vessel owner or operator and the third-party service provider must provide the EM data for any given trip to NMFS, and its authorized officers and designees, upon request including, but not limited to, trips selected for NMFS review. For fishing year 2024, each audit model vessel's EM video footage review rate will be calculated individually based on that vessel's performance during the fishing year. The minimum possible EM video footage review rate will be 35 percent of sector trips for audit model vessels. Vessels that are new to EM will have a 50-percent video footage review rate in 2024 to allow more opportunities for feedback on their catch handling and reporting performance.

All sectors that harvest fish included an ASM plan as part of their approved operations plans. Sectors that operate only as permit banks, and explicitly prohibit fishing in their operations plans, are not required to include provisions for an ASM program. Nine sectors use the NMFS-designed ASM program, and four sectors use a sector-designed ASM program, previously approved by NMFS. Thirteen sectors also included an EM plan as part of their approved operations plans. All of these sectors included the NMFS-designed audit model EM program in their operations plans. Eleven of these sectors also included the NMFS-designed maximized retention EM program in their operations plans. The MREM program will remain in these approved sector operations plans. However, as explained above, NMFS will not operate MREM in fishing year 2024 and, as such, will not approve vessel-specific monitoring plans to enroll in the MREM program.

Approved Exemptions Granted for Fishing Years 2024

NMFS previously granted exemptions from the following requirements for fishing years 2023 and 2024 (88 FR 26502; May 1, 2023), all of which were also requested and granted in previous years:

(1) 120-day block out of the fishery required for Day gillnet vessels;

(2) 20-day spawning block out of the fishery required for all vessels;

(3) Limits on the number of gillnets for Day gillnet vessels outside the GOM;

(4) Prohibition on a vessel hauling another vessel's gillnet gear;

(5) Limits on the number of gillnets that may be hauled on GB when fishing under a Northeast multispecies/monkfish DAS;

(6) Limits on the number of hooks that may be fished;

(7) DAS Leasing Program length and horsepower restrictions;

(8) Prohibition on discarding;

(9) Gear requirements in the Eastern U.S./Canada Management Area;

(10) Prohibition on a vessel hauling another vessel's hook gear;

(11) The requirement to declare an intent to fish in the Eastern U.S./Canada Special Access Program (SAP) and the Closed Area (CA) II Yellowtail Flounder/Haddock SAP prior to leaving the dock;

(12) Seasonal restrictions for the Eastern U.S./Canada Haddock SAP;

(13) Seasonal restrictions for the CA II Yellowtail Flounder/Haddock SAP;

(14) Sampling exemption;

(15) Prohibition on combining small-mesh exempted fishery and sector trips in SNE;

(16) Extra-large mesh requirement to target dogfish on trips excluded from ASM in SNE and Inshore GB;

(17) Requirement that Handgear A vessels carry a Vessel Monitoring System unit when fishing in a single broad stock area; and

(18) Limits on the number of gillnets for Day gillnet vessels in the GOM.

Exemption Requests in Fishing Year 2024

For fishing year 2024, sectors did not request any novel exemptions.

Classification

NMFS is issuing this rule pursuant to 305(d) of the Magnuson-Stevens Act because this action is necessary to carry out the Northeast Multispecies FMP in accordance with the FMP's implementing regulations. The NMFS Assistant Administrator has determined that this rule is consistent with the Northeast Multispecies FMP, other provisions of the Magnuson-Stevens Act, and other applicable law.

Pursuant to 5 U.S.C. 553(b)(B), the Assistant Administrator for Fisheries finds good cause to waive prior public notice and an opportunity for public comment, because allowing time for notice and comment is impracticable, unnecessary, and contrary to the public interest. The allocations in this action are required by regulations that prescribe how they are determined. The public had a prior opportunity to comment on this process and the formula used for its calculation during the development of the rules implementing the Northeast Multispecies FMP and subsequent amendments and framework adjustments. Thus, in accordance with the existing regulations, NMFS calculates a sector's allocation for each stock by summing its members' PSC for a stock and then multiplying that total percentage by the available commercial sub-ACL for that stock. Thus, the ACE allocations are based on long-established fishing histories and are formulaic, administrative, and involve no exercise of discretion.

NMFS finds, pursuant to 5 U.S.C. 553(d)(3), that there is good cause to waive the 30-day delay in the date of effectiveness for this final rule. This action allocates ACE to groundfish sectors in the Northeast multispecies fishery for fishing year 2024. Sectors are prohibited from fishing without ACE allocations; as such, timely implementation is necessary to ensure that sectors may fish at the start of the 2024 fishing year on May 1, 2024. If sectors were prohibited from fishing while waiting for the rule to take effect, there would be significant disruption to the fishery along with negative economic impacts, thus undermining the intent of the rule. The allocation of ACE to groundfish sectors occurs annually. Industry members and other stakeholders are aware of and familiar with these proceedings and expect them to occur in a timely manner.

This final rule is exempt from review under Executive Order 12866 because it contains no implementing regulations.

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

Because prior notice and the opportunity for public comment are not required for this action by the Administrative Procedure Act (5 U.S.C. 551 *et seq.*), or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* are inapplicable. Therefore, no final regulatory flexibility analysis is required and none has been prepared.

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

Dated: April 2, 2024.

Samuel D. Rauch III,

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

[FR Doc. 2024–07296 Filed 4–4–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

[RTID 0648–XD790]

Pacific Island Fisheries; 2024 Northwestern Hawaiian Islands Lobster Harvest Guideline

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

ACTION: Notification of lobster harvest guideline.

SUMMARY: NMFS establishes the annual harvest guideline for the commercial lobster fishery in the Northwestern Hawaiian Islands (NWHI) for calendar year 2024 at zero lobsters.

DATES: April 5, 2024.

FOR FURTHER INFORMATION CONTACT: Keith Kamikawa, NMFS Pacific Island Regional Office (PIRO) Sustainable Fisheries, 808–725–5177.

SUPPLEMENTARY INFORMATION: NMFS manages the NWHI commercial lobster fishery under the Fishery Ecosystem Plan for the Hawaii Archipelago. The regulations at 50 CFR 665.252(b) require NMFS to publish an annual harvest guideline for lobster in Crustacean Permit Area 1, comprised of Federal waters around the NWHI.

Regulations governing the Papahānaumokuākea Marine National Monument in the NWHI prohibit the unpermitted removal of monument resources (50 CFR 404.7), and establish a zero annual harvest guideline for lobsters (50 CFR 404.10(a)). Accordingly, NMFS establishes the harvest guideline for the NWHI commercial lobster fishery for calendar year 2024 at zero lobsters. Harvest of NWHI lobster resources is not allowed.

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

Dated: March 27, 2024.

Everett Wayne Baxter,

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

[FR Doc. 2024–06917 Filed 4–4–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 240227–0061]

RTID 0648–XD694

Fisheries of the Exclusive Economic Zone Off Alaska; Pollock in Statistical Area 610 in the Gulf of Alaska

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for pollock in Statistical Area 610 in the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the A season allowance of the 2024 total allowable catch (TAC) of pollock for Statistical Area 610 in the GOA.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), April 2, 2024, through 1200 hrs, A.l.t., May 31, 2024.

FOR FURTHER INFORMATION CONTACT: Adam Zaleski, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North

Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The A season allowance of the 2024 TAC of pollock in Statistical Area 610 of the GOA is 5,422 metric tons (mt) as established by the final 2024 and 2025 harvest specifications for groundfish in the GOA (89 FR 15484, March 4, 2024) and correction (89 FR 18835, March 15, 2024).

In accordance with §§ 679.20(d)(1)(i) and 679.20(d)(1)(ii)(B), the Regional Administrator has determined that the A season allowance of the 2024 TAC of pollock in Statistical Area 610 of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 5,322 mt and is setting aside the remaining 100 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for pollock in Statistical Area 610 of the GOA.

While this closure is effective, the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion, and would delay the closure of pollock in Statistical Area 610 in the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of April 01, 2024.

The Assistant Administrator for Fisheries, NOAA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

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

Dated: April 1, 2024.

Everett Wayne Baxter,

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

[FR Doc. 2024–07252 Filed 4–2–24; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 89, No. 67
Friday, April 5, 2024

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–0992; Project Identifier MCAI–2024–00030–T]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2019–21–01, which applies to all Airbus SAS Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes). AD 2019–21–01 requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. Since the FAA issued AD 2019–21–01, the FAA has determined that new or more restrictive airworthiness limitations are necessary. This proposed AD would require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by May 20, 2024.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–0992; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For EASA material that is proposed for IBR in this NPRM, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu*.
- For Airbus SAS material, contact Airbus SAS, Airworthiness Office—EAW, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* website *airbus.com.*
- You may view this material that is incorporated by reference at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2024–0992.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 206–231–3225; email: *dan.rodina@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2024–0992; Project Identifier MCAI–2024–00030–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Dan Rodina, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 206–231–3225; email: *dan.rodina@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2019–21–01, Amendment 39–19767 (84 FR 56935, October 24, 2019) (AD 2019–21–01), for all Airbus SAS Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes). AD 2019–21–01 was prompted by an MCAI originated by EASA, which is the Technical Agent for the Member States of the European Union. EASA issued AD 2019–0090, dated April 26, 2019

(EASA AD 2019–0090) (which corresponds to FAA AD 2019–21–01), to correct an unsafe condition.

AD 2019–21–01 requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. The FAA issued AD 2019–21–01 to address fatigue cracking, damage, and corrosion in principal structural elements, which could result in reduced structural integrity of the airplane. AD 2019–21–01 specifies that accomplishing the revision required by that AD terminates all requirements of AD 2018–01–07, Amendment 39–19148 (83 FR 2042, January 16, 2018) (AD 2018–01–07) and AD 2018–19–33, Amendment 39–19434 (83 FR 48932, September 28, 2018) (AD 2018–19–33). This proposed AD would therefore continue to allow that terminating action.

Actions Since AD 2019–21–01 Was Issued

Since the FAA issued AD 2019–21–01, EASA superseded AD 2019–0090 and issued EASA AD 2024–0009, dated January 9, 2024 (EASA AD 2024–0009) (also referred to as the MCAI), for all Airbus SAS Model A300–600 airplanes. The MCAI states that new or more restrictive airworthiness limitations have been developed.

The FAA is proposing this AD to address the unsafe condition on these products. You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–0992.

Related Service Information Under 1 CFR Part 51

The FAA reviewed EASA AD 2024–0009. This service information specifies new or more restrictive airworthiness limitations for airplane structures and safe life limits.

This proposed AD also would also require Airbus A300–600 Airworthiness Limitations Section (ALS), Part 2, ''Damage Tolerant Airworthiness Limitation Items (DT–ALI),'' Revision 03, dated December 14, 2018, which the Director of the Federal Register approved for incorporation by reference as of November 29, 2019 (84 FR 56935, October 24, 2019).

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

FAA's Determination

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would retain all requirements of AD 2019–21–01. This proposed AD would also require revising the existing maintenance or inspection program, as applicable, to incorporate additional new or more restrictive airworthiness limitations, which are specified in EASA AD 2024–0009 already described, as proposed for incorporation by reference. Any differences with EASA AD 2024–0009 are identified as exceptions in the regulatory text of this AD.

This proposed AD would require revisions to certain operator maintenance documents to include new actions (*e.g.,* inspections). Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this proposed AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance (AMOC) according to paragraph (m)(1) of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2024–0009 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2024–0009 through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2024–0009 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2024–0009. Service information required by EASA AD 2024–0009 for compliance will be available at *regulations.gov* by searching for and locating Docket No. FAA–2024–0992 after the FAA final rule is published.

Airworthiness Limitation ADs Using the New Process

The FAA's process of incorporating by reference MCAI ADs as the primary source of information for compliance with corresponding FAA ADs has been limited to certain MCAI ADs (primarily those with service bulletins as the primary source of information for accomplishing the actions required by the FAA AD). However, the FAA is now expanding the process to include MCAI ADs that require a change to airworthiness limitation documents, such as airworthiness limitation sections.

For these ADs that incorporate by reference an MCAI AD that changes airworthiness limitations, the FAA requirements are unchanged. Operators must revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in the new airworthiness limitation document. The airworthiness limitations must be followed according to 14 CFR 91.403(c) and 91.409(e).

The previous format of the airworthiness limitation ADs included a paragraph that specified that no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions and intervals are approved as an AMOC in accordance with the procedures specified in the AMOCs paragraph under ''Additional AD Provisions.'' This new format includes a ''New Provisions for Alternative Actions and Intervals'' paragraph that does not specifically refer to AMOCs, but operators may still request an AMOC to use an alternative action or interval.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 120 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate

is more accurate than a per-airplane estimate.

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) AD 2019–21–01, Amendment 39–19767 (84 FR 56935, October 24, 2019); and

■ b. Adding the following new AD:

Airbus SAS: Docket No. FAA–2024–0992; Project Identifier MCAI–2024–00030–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by May 20, 2024.

(b) Affected ADs

This AD replaces AD 2019–21–01, Amendment 39–19767 (84 FR 56935, October 24, 2019) (AD 2019–21–01).

(c) Applicability

This AD applies to all Airbus SAS Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes), certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address fatigue cracking, damage, and corrosion in principal structural elements. The unsafe condition, if not addressed, could result in reduced structural integrity of the airplane.

(f) Compliance

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

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

This paragraph restates the requirements of paragraph (g) of AD 2019–21–01, with no changes. Within 90 days after November 29, 2019 (the effective date of AD 2019–21–01), revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in Airbus A300–600 Airworthiness Limitations Section (ALS), Part 2, ''Damage Tolerant Airworthiness Limitation Items (DT–ALI),'' Revision 03, dated December 14, 2018. The initial compliance time for doing the tasks is at the time specified in Airbus A300–600 Airworthiness Limitations Section (ALS), Part 2, ''Damage Tolerant Airworthiness Limitation Items (DT–ALI),'' Revision 03, dated December 14, 2018, or within 90 days after November 29, 2019 (the effective date of AD 2019–21–01), whichever occurs later. Accomplishing the revision of the existing maintenance or inspection program required by paragraph (i) of this AD terminates the requirements of this paragraph.

(h) Retained Restrictions on Alternative Actions or Intervals With a New Exception

This paragraph restates the requirements of paragraph (h) of AD 2019–21–01, with a new exception. Except as required by paragraph (i) of this AD: After the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions and intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (m)(1) of this AD.

(i) New Revision of the Existing Maintenance or Inspection Program

Except as specified in paragraph (j) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2024–0009, dated January 9, 2024 (EASA AD 2024–0009). Accomplishing the revision of the existing maintenance or inspection program required by this paragraph terminates the requirements of paragraph (g) of this AD.

(j) Exceptions to EASA AD 2024–0009

(1) This AD does not adopt the requirements specified in paragraphs (1) and (2) of EASA AD 2024–0009.

(2) Paragraph (4) of EASA AD 2024–0009 specifies revising ''the approved AMP,'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(3) The initial compliance time for doing the tasks specified in paragraph (4) of EASA AD 2024–0009 is at the applicable ''limitations'' and ''associated thresholds'' as incorporated by the requirements of paragraph (4) of EASA AD 2024–0009, or within 90 days after the effective date of this AD, whichever occurs later.

(4) This AD does not adopt the provisions specified in paragraphs (5) and (6) of EASA AD 2024–0009.

(5) This AD does not adopt the ''Remarks'' section of EASA AD 2024–0009.

(k) New Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (i) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2024–0009.

(l) Terminating Action for AD 2019–21–01

Accomplishing the actions required by this AD terminates all requirements of AD 2019–21–01.

(m) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (n) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (m)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(n) Additional Information

For more information about this AD, contact Dan Rodina, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 206–231–3225; email: *dan.rodina@faa.gov.*

(o) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on [DATE 35 DAYS AFTER PUBLICATION OF THE FINAL RULE].

(i) European Union Aviation Safety Agency (EASA) AD 2024–0009, dated January 9, 2024.

(ii) [Reserved]

(4) The following service information was approved for IBR on November 29, 2019 (84 FR 56935, October 24, 2019).

(i) Airbus A300–600 Airworthiness Limitations Section (ALS), Part 2, ''Damage Tolerant Airworthiness Limitation Items (DT–ALI),'' Revision 03, dated December 14, 2018.

(ii) [Reserved]

(5) For EASA AD 2024–0009, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

(6) For Airbus SAS material, contact Airbus SAS, Airworthiness Office—EAW, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* website *airbus.com.*

(7) You may view this material that is incorporated by reference at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(8) You may view this material at 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.*

Issued on March 28, 2024.

Victor Wicklund,

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

[FR Doc. 2024–06994 Filed 4–4–24; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 284

[Docket No. RM96–1–043]

Standards for Business Practices of Interstate Natural Gas Pipelines

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Energy Regulatory Commission proposes to amend its regulations to incorporate by reference, with certain enumerated exceptions, the latest version (Version 4.0) of Standards for Business Practices of Interstate Natural Gas Pipelines adopted by the Wholesale Gas Quadrant of the North American Energy Standards Board (NAESB).

DATES: Comments are due June 4, 2024.

ADDRESSES: Comments, identified by docket number, may be filed in the following ways. Electronic filing through *https://www.ferc.gov/* is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.
- For those unable to file electronically, comments may be filed by U.S. Postal Service mail or by hand (including courier) delivery.

○ *Mail via U.S. Postal Service Only:* Addressed to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

○ *Hand (Including Courier) Delivery:* Deliver to: Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

The Comment Procedures section of this document contains more detailed filing procedures.

FOR FURTHER INFORMATION CONTACT:

Jerry Chiang (Technical Issues), Office of Energy Policy and Innovation, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8786

Oscar F. Santillana (Technical Issues), Office of Energy Market Regulation, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–6392

Carla Pettus (Legal Issues), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8361

SUPPLEMENTARY INFORMATION:

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I. Overview

1. The Federal Energy Regulatory Commission (Commission) proposes to amend its regulations at 18 CFR 284.12 to incorporate by reference, with certain enumerated exceptions,[1] the latest version (Version 4.0) of Standards for Business Practices of Interstate Natural Gas Pipelines adopted by the Wholesale Gas Quadrant (WGQ) of the North American Energy Standards Board (NAESB) applicable to interstate natural gas pipelines. NAESB is an American National Standards Institute-accredited, non-profit standards development organization formed for the purpose of developing voluntary standards and model business practices that promote more competitive and efficient natural gas and electric markets. On October 2, 2023, NAESB filed a notice that it had approved Version 4.0 to replace the currently incorporated version (Version 3.2) of those business practice standards (Informational Report).[2] The implementation of these standards and regulations will promote greater efficiency and reliability of the natural gas industries' operations and strengthen the cybersecurity protections provided within the standards.[3]

II. Background

2. Since 1996, the Commission has adopted in its regulations NAESB's business practice standards and communication methodologies of interstate natural gas pipelines to create a more integrated and efficient pipeline network system. These regulations have been promulgated in the Order No. 587 series of orders,[4] wherein the Commission incorporated by reference the standards for interstate natural gas pipeline business practices and electronic communications developed by NAESB's WGQ. Upon incorporation by reference, this version of the standards will replace the currently incorporated version (Version 3.2) of those business practice standards.

3. On October 2, 2023, NAESB filed a report informing the Commission that it had adopted and ratified WGQ Version 4.0 of its business practice standards applicable to interstate natural gas pipelines. WGQ Version 4.0 includes business practice standards developed and modified in response to industry requests and directives from the NAESB Board of Directors. This version also includes the standards developed in response to the recommendations of Sandia National Laboratory (Sandia),[5] which in 2019 issued a cybersecurity surety assessment of the NAESB standards sponsored by DOE.[6]

4. The NAESB Informational Report identifies all the changes made to the WGQ Version 3.2 standards and summarizes the deliberations that led to the changes. It also identifies changes to the existing standards that were considered but not adopted due to a lack of consensus or other reasons.

III. Discussion

5. In this notice of proposed rulemaking (NOPR), we propose to incorporate by reference, in our regulations, Version 4.0 of the NAESB WGQ consensus business practice standards, with certain exceptions.[7] In the subsections that follow, we provide the summary required by the Office of Federal Register regulations. As an initial matter, we note that the WGQ Version 4.0 Standards include modifications, reservations, and additions to the following set of existing WGQ Standards, *i.e.,* the Version 3.2 Business Practice Standards. (Each set of Business Practice Standards is referred to as a manual.)

Business Practice Standards
- Additional Standards
- Flowing Gas Related Standards
- Invoicing Related Standards
- Quadrant Electronic Delivery Mechanism Standards
- Capacity Release Related Standards
- Contracts Related Standards
- WGQ/REQ/RGQ Internet Electronic Transport

Additionally, the WGQ Version 4.0 Business Practice Standards include one new manual of standards:

Cybersecurity Related Standards

6. We propose that compliance filings made in accordance with a final rule be made 120 days after issuance of a final rule in this proceeding or, if the compliance filing date falls on a weekend or holiday, on the first business day thereafter, with an effective date 180 days from the date compliance filings are due in this proceeding or, if the effective date falls on a weekend or holiday, the first business day thereafter.

7. As the Commission found in Order No. 587, adoption of consensus standards is appropriate, because the consensus process helps ensure the reasonableness of the standards by requiring that the standards draw support from a broad spectrum of industry participants representing all segments of the industry. Moreover, because the industry conducts business under these standards, the Commission's regulations should reflect

[1] As explained below, we are not proposing in this proposed rule to incorporate by reference the two new model addendums supporting the NAESB Base Contract for the Sale and Purchase of Natural Gas, NAESB WGQ Standard 6.3.1.RG Renewable Natural Gas Addendum and WGQ Standard 6.3.1.CG Certified Gas Addendum, included in the NAESB WGQ Version 4.0 package of business practice standards.

[2] *See* NAESB WGQ Business Practice Standards Version 4.0 Report, Docket No. RM96–1–043, (Oct. 2, 2023).

[3] As explained below, NAESB has developed and adopted, in conjunction with Sandia National Laboratories, a series of business practice standards to strengthen the cybersecurity protections provided within the standards.

[4] This series of orders began with the Commission's issuance of *Standards for Bus. Practices of Interstate Nat. Gas Pipelines,* Order No. 587, 61 FR 39053 (July 26, 1996), FERC Stats. & Regs. ¶ 31,038 (1996) (cross-referenced at 76 FERC ¶ 61,042).

[5] Sandia is a multidisciplinary national laboratory and federally funded research and development center for the U.S. Department of Energy's (DOE) National Nuclear Security Administration that supports numerous federal, state, and local government agencies, companies, and organizations.

[6] In April 2017, NAESB announced that Sandia, through funding provided by DOE, would be performing a surety assessment of the NAESB standards. As determined by Sandia and DOE, the purpose of the surety assessment was to analyze cybersecurity elements within the standards, focusing on four areas: (1) the NAESB Certification Program for Accredited Certification Authorities, including the Wholesale Electric Quadrant (WEQ)–012 Public Key Infrastructure Business Practice Standards, the NAESB Accreditation Requirements for Authorized Certificate Authorities, and the Authorized Certification Authority Process; (2) the WEQ Open Access Same-Time Information Systems suite of standards; (3) the WGQ and Retail Markets Quadrant internet Electronic Transport (IET) and Quadrant Electronic Delivery Mechanism (EDM) Related Standards Manual; and (4) a high-level dependency analysis between the gas and electric markets to evaluate the different security paradigms the markets employ.

[7] In the discussion below we identify the NAESB WGQ Version 4.0 Standards that we propose *not* to incorporate by reference.

those standards that have the widest possible support. In section 12(d) of the National Technology Transfer and Advancement Act of 1995, Congress affirmatively requires Federal Agencies to use technical standards developed by voluntary consensus standards organizations, like NAESB, to carry out policy objectives or activities.

8. We discuss below some specific aspects of NAESB's Informational Report.

A. Modifications to Previous Version of Standards

1. WGQ Cybersecurity Related Standards

9. WGQ Version 4.0 added a new standards manual for NAESB cybersecurity-related standards. This new set of standards consolidates existing NAESB cybersecurity-related standards into a single manual. This consolidation should make the NAESB and Commission processes for revising NAESB cybersecurity standards easier and faster to help match the fast pace of changes in cybersecurity practices. These standards focus on strengthening the cybersecurity practices utilized by the industry through the mitigation of potential vulnerabilities and the use of secure communication and encryption methodologies.

2. Other Standards Modifications

10. In response to industry request, Version 4.0 adds new data elements to the WGQ Additional Standards and Capacity Release Related Standards and modifies existing data elements in the Flowing Gas Related Standards and Invoicing Related Standards to improve efficiencies of business processes for transportation service providers [8] and parties interacting with these entities.

11. NAESB revised the WGQ Additional Standards by adding a new data element, ''Cycle Indicator,'' to the data set for the Storage Information standard to address technical details for reporting natural gas storage balances and the activities that affect storage balances. NAESB states the new sender's option data element ''Cycle Indicator'' will support the reporting of storage information data for each cycle while also allowing parties receiving such information to distinguish between the data more easily for individual transactions.[9]

12. NAESB revised the Flowing Gas Related Business Practice Standards to change the ''Service Requester Contract'' data element from ''not used'' to ''mutually agreed,'' for allocation of natural gas between parties under two pre-determined allocation transaction types, found within the allocation matrix included as part of WGQ Standard 2.4.3.[10]

13. NAESB revised the WGQ Invoicing Related Standards by modifying the ''Charge Type Rate'' data element contained in the data set for the Transportation/Sales Invoice standard to allow for the identification of multiple rates that may be applicable for a single transaction or service. The modification to the data element allows transportation service providers to use a ''null'' value in circumstances where information describing the applicable charge type rate is included as part of miscellaneous notes. NAESB states this change will allow transportation service providers to make available a summary of the amount due for each line item of an invoice with detailed, breakout information regarding the applicable rate and make it easier for a customer to ascertain the final charge amount.[11]

14. NAESB revised the Capacity Release Related Standards by adding a new sender's option data element, ''Location Indicator Data,'' to the Transactional Reporting—Capacity Release standard to provide a mechanism for a transportation service provider to communicate the locations at which a discounted rate is offered as well as if the rate is associated with a single location, multiple locations, or all locations.

B. Standards Proposed Not To Be Incorporated by Reference

15. We propose to continue our past practice [12] of not incorporating by reference into our regulations any optional model contracts because we do not require the use of these contracts.[13] In addition, consistent with our findings in past proceedings, we are not proposing to incorporate by reference the Wholesale Electric Quadrant/WGQ eTariff Related Standards because the Commission has previously adopted and posted its standards and protocols for electronic tariff filings based on NAESB standards.[14]

C. Proposed Implementation Procedures

16. We propose to continue the compliance filing requirements as revised and prescribed in Order No. 587–V to increase the transparency of the interstate natural gas pipelines' incorporation by reference of the NAESB WGQ Standards so that shippers and the Commission will know which tariff provision(s) implements each standard as well as the status of each standard.[15]

17. We propose that compliance filings made in accordance with a final rule be made 120 days after issuance of a final rule in this proceeding or, if the compliance filing date falls on a weekend or holiday, on the first business day thereafter, with an effective date 180 days from the date compliance filings are due in this proceeding or, if the effective date falls on a weekend or holiday, the first business day thereafter. As the Commission found in Order No. 587–V, adoption of the revised compliance filing requirements increases the transparency of the interstate natural gas pipelines' incorporation by reference of the NAESB WGQ Standards so that shippers and the Commission will know which tariff provision(s) implements each standard as well as the status of each standard.[16]

18. Consistent with the Commission's practice since Order No. 587–V, each interstate natural gas pipeline must designate a single tariff section under which every NAESB WGQ Standard incorporated by reference by the Commission is listed.[17] For each standard, the pipeline must specify in the tariff section or tariff record(s) listing all the NAESB standards:

(a) whether the standard is incorporated by reference;

(b) for those standards not incorporated by reference, the tariff provision that complies with the standard; or

(c) for those standards with which the pipeline does not comply, an explanatory statement, including an indication of whether the pipeline has been granted a waiver, extension of

[8] Natural gas transportation service is provided by interstate pipelines, intrastate pipelines, natural gas gathering pipelines, and local distribution companies; all are referred to as ''transportation service providers.''

[9] Informational Report at 4.

[10] The matrix identifies the data elements needed to communicate the results of the allocation process.

[11] Informational Report at 5.

[12] *See, e.g., Standards for Bus. Practices of Interstate Nat. Gas Pipelines,* Notice of Proposed Rulemaking, 86 FR 12879 (Mar. 5, 2021), 174 FERC ¶ 61,103, at P 19 (2021) (*Version 3.2 NOPR*).

[13] *Id.; Standards for Bus. Practices of Interstate Nat. Gas Pipelines,* Order No. 587–V, 77 FR 43711 (Jul. 26, 2012), 140 FERC ¶ 61,036, at P 11 n.11 (2012).

[14] *Version 3.2 NOPR,* 174 FERC ¶ 61,103 at P 19; *Elec. Tariff Filings,* Order No. 714, 73 FR 57515 (Oct. 3, 2008), 124 FERC ¶ 61,270 (2008).

[15] Order No. 587–V, 140 FERC ¶ 61,036 at PP 36–39.

[16] *Trans-Union Interstate Pipeline L.P.,* 141 FERC ¶ 61,167, at P 36 (2012) (Order No. 587–V Compliance Order).

[17] *Id.* P 36; *Version 3.2 NOPR,* 174 FERC ¶ 61,103 at P 21.

time, or other variance with respect to compliance with the standard.[18]

19. Likewise, consistent with past practice, we will post on our eLibrary website (under Docket No. RM96–1–043) a sample tariff format, to provide filers with an illustrative example to aid them in preparing their compliance filings.

20. Consistent with our policy since Order No. 587–V,[19] entities may request waivers under the requirements set forth in Order No. 587–V and the Commission will then evaluate those requests at that time.[20]

21. If the pipeline is requesting a continuation of an existing waiver or extension of time, it must include a table in its transmittal letter that identifies the standard for which the Commission granted a waiver or extension of time, and the docket number or order citation to the proceeding in which the Commission granted the waiver or extension of time. The pipeline also must present an explanation for why such waiver or extension of time should remain in force with regard to the WGQ Version 4.0 Standards.

22. This continues the Commission's practice of having pipelines include in their tariffs a common location that identifies the way in which the pipeline is incorporating all the NAESB WGQ Standards and the standards with which it is required to comply.

IV. Notice of Use of Voluntary Consensus Standards

23. Office of Management and Budget Circular A 119 (February 10, 1998) provides that Federal Agencies should publish a request for comment in a NOPR when the agency is seeking to issue or revise a regulation proposing to adopt a voluntary consensus standard or a government-unique standard. In this NOPR, we are proposing to incorporate by reference voluntary consensus standards developed by the WGQ.

V. Incorporation by Reference

24. The Office of the Federal Register requires agencies proposing to incorporate material by reference to discuss the ways that the materials it incorporates by reference are reasonably available to interested parties and how interested parties can obtain the materials. The regulations also require agencies to summarize, in the preamble of the final rule, the material that it incorporates by reference. The standards we are proposing to incorporate by reference consist of seven suites of NAESB WGQ Business Practice Standards that address a variety of topics and are designed to streamline the transactional processes for the wholesale natural gas industry by promoting a more competitive and efficient market. These include the WGQ Additional Business Practice Standards, WGQ Nominations Related Business Practice Standards, WGQ Flowing Gas Related Standards, WGQ Invoicing Related Business Practice Standards, Quadrant Electronic Delivery Mechanism Related Business Practice Standards, Capacity Release Related Business Practice Standards, and WGQ Cybersecurity Related Standards. We summarize these standards below.

25. *The WGQ Additional Standards* address six areas: Creditworthiness; Storage Information; Gas/Electric Operational Communications; Operational Capacity; Unsubscribed Capacity; and Location Data Download.

- The Creditworthiness related standards describe requirements for the exchange of information, notification, and communication between parties during the creditworthiness evaluation process.
- The Storage Information related standards define the information to be provided to natural gas service requesters related to storage activities and/or balances.
- The Gas/Electric Operational Communications related standards define communication protocols intended to improve coordination between the natural gas and electric industries in daily operational communications between gas transportation service providers and gas-fired power plants. These standards include requirements for communicating anticipated power generation fuel needs for the upcoming day as well as any operating problems that might hinder gas-fired power plants from receiving contractual gas quantities.
- The Operational Capacity related standards define requirements for the transportation service provider's reporting of its operational capacity, total scheduled quantity, and operationally available capacity.
- The Unsubscribed Capacity related standards define requirements for the transportation service provider's reporting of its available unsubscribed capacity.
- The Location Data Download related standards define requirements for the use of codes assigned by the transportation service provider for locations and common codes for parties communicating electronically.

26. *The WGQ Nominations Related Standards* define the process by which a natural gas service requester with a natural gas transportation contract nominates (or requests) service from a pipeline or a transportation service provider for the delivery of natural gas.

27. *The WGQ Flowing Gas Related Standards* define the business processes related to the communication of entitlement rights of flowing gas at a location, of the entitlement rights on a contractual basis, of the management of imbalances, and of the measurement and gas quality information of the actual flow of gas.

28. *The WGQ Invoicing Related Standards Manual* defines the process for the communication of charges for services rendered (Invoice), communication of details about funds rendered in payment for services rendered (Payment Remittance), and communication of the financial status of a customer's account (Statement of Account).

29. *The WEQ Quadrant Electronic Delivery Mechanism Related Standards* define the framework for the electronic dissemination and communication of information between parties in the North American wholesale gas marketplace for Electronic Data Interchange/EDM transfers, batch flat file/EDM transfers, informational postings websites, Electronic Bulletin Boards/EDM, and interactive flat file/EDM.

30. *The WEQ Capacity Release Related Standards* define the business processes for communication of information related to the selling of all or any portion of a transmission service requester's contract rights.

31. *The WEQ Internet Electronic Transport Related Standards* define the implementation of various technologies necessary to communicate transactions and other electronic data using standard protocols for electronic commerce over the internet between trading partners.

32. *The WGQ Cybersecurity Related Standards Manual* defines the requirements for ensuring the security of electronic communications and transactions among parties. Commission regulations provide that copies of the standards incorporated by reference may be obtained through purchase or otherwise from the North American Energy Standards Board, 801 Travis Street, Suite 1675, Houston, TX 77002, Phone: (713) 356–0060, website: *http://*

[18] Shippers can use the Commission's electronic tariff system to locate the tariff record containing the NAESB standards, which will indicate the docket in which any waiver or extension of time was granted.

[19] Order No. 587–V, 140 FERC ¶ 61,036.

[20] Order No. 587–V Compliance Order, 141 FERC ¶ 61,167 at PP 4, 38 (a pipeline does not need to seek a waiver for standards that address business practices that the pipeline does not offer).

www.naesb.org/. The standards can also be reviewed without purchasing them.

33. The procedures used by NAESB make its standards reasonably available to those affected by Commission regulations, which generally is comprised of entities that have the means to acquire the information they need to effectively participate in Commission proceedings. Participants can join NAESB, for an annual membership cost of $8,000, which entitles them to full participation in NAESB and enables them to obtain these standards at no additional cost. Non-members may obtain any of the ten individual standards manuals for $250 per manual, which in the case of these standards would total $2,500 for all ten manuals. Non-members also may obtain the complete set of Standards Manuals for $2,000.

34. NAESB provides ample opportunities for non-members, including agents, subsidiaries, and affiliates of NAESB members, to obtain access to the copyrighted standards through a no-cost limited copyright waiver. The limited copyright waivers are issued by the NAESB office and are granted to non-members on a case-by-case basis for the purpose of evaluating standards prior to purchase and/or reviewing the standards to prepare comments to a regulatory agency. Following the granting of a limited copyright waiver, the non-member is provided with read-only access to the standards through the end of the comment period or some other set period of time via Locklizard Safeguard Secure Viewer.[21] NAESB will grant one limited copyright waiver per company for each set of standards or final actions. Any entity seeking a limited copyright waiver should contact the NAESB office.

VI. Information Collection Statement

35. The Office of Management and Budget (OMB) regulations require that OMB approve certain reporting, record keeping, and public disclosure requirements (information collection) imposed by an agency.[22] Therefore, we are submitting our proposed information collection to OMB for review in accordance with section 3507(d) of the Paperwork Reduction Act of 1995. Upon approval of a collection of information, OMB will assign an OMB control number and an expiration date. Respondents subject to the filing requirements of a rule will not be penalized for failing to respond to these collections of information unless the collection of information displays a valid OMB control number.

36. We solicit comments on our need for this information, whether the information will have practical utility, the accuracy of the provided burden estimates, ways to enhance the quality, utility, and clarity of the information to be collected, and any suggested methods for minimizing respondents' burden, including the use of automated information techniques.

37. *Public Reporting Burden:* The Commission's burden estimates for the proposals in this NOPR are for one-time implementation of the information collection requirements of this NOPR (including tariff filing, documentation of the process and procedures, and information technology work).

38. The collections of information related to this NOPR fall under FERC–545 (Gas Pipeline Rates: Rate Change (Non-Formal))[23] and FERC–549C (Standards for Business Practices of Interstate Natural Gas Pipelines).[24] The following estimates of reporting burden are related only to this NOPR and anticipate the costs to interstate natural gas pipelines for compliance with our proposals in this NOPR. The burden estimates are primarily related to implementing these standards and regulations and will not result in ongoing costs.

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	Number of respondents[25]	Annual number of responses per respondent	Total number of responses	Average burden hr. per response	Total annual burden hours & total annual cost[26]	Annual costs per respondent ($)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) / (1) = (6)
FERC–545 (one-time)	193	1	193	10 hrs.; $1,010	1,930 hrs.; $194,930	$1,010
FERC–549C (one-time)	193	1	193	100 hrs.; $10,100	19,300 hrs.; $1,949,300	10,100
Total			386		21,230 hrs.; $1,977,580	

The one-time burden (for both the FERC–545 and FERC–549C) would take place in Year 1 as follows:

FERC–545: 193 entities × 1 response/entity (10 hours/response × $101/hour) = $194,930

FERC–549C: 193 entities × 1 response/entity (100 hours × $101/hour) = $1,949,300

The responses and burden for Years 1–2 would total respectively as follows:

Year 1: 97 responses; 970 hours (FERC–545); 9,700 hours (FERC–549C)

Year 2: 96 responses; 960 hours (FERC–545); 9,600 hours (FERC–549C)

Title: FERC–545, Gas Pipeline Rates: Rates Change (Non-Formal); FERC–549C, Standards for Business Practices of Interstate Natural Gas Pipelines.

Action: Proposed information collections.

OMB Control Nos.: 1902–0154 (FERC–545), 1902–0174 (FERC–549C).

Respondents: Business or other for profit (*e.g.,* Natural Gas Pipelines, applicable to only a few small businesses).

[21] For more information on Locklizard, please refer to the company's website: *https://www.locklizard.com.*

[22] 5 CFR 1320.11 (2020).

[23] FERC–545 covers rate change filings made by natural gas pipelines, including tariff changes.

[24] FERC–549C covers Standards for Business Practices of Interstate Natural Gas Pipelines.

[25] The number of respondents is the number of entities in which a change in burden from the current standards to the proposed exists, not the total number of entities from the current or proposed standards that are applicable.

[26] The estimated hourly cost (salary plus benefits) provided in this section is based on the salary figures for May 2022 posted on April 25, 2023 by the Bureau of Labor Statistics for the Utilities sector (*https://www.bls.gov/oes/current/naics3_221000.htm*) and scaled to reflect benefits using the relative importance of employer costs for employee compensation from September 12, 2023 (*https://www.bls.gov/news.release/ecec.nr0.htm*). The hourly estimates for salary plus benefits are:

Computer and Information Systems Manager (Occupation Code: 11–3021), $101.58.

Computer and Information Analysts (Occupation Code: 15–1120(1221), $87.42.

Electrical Engineer (Occupation Code: 17–2071), $70.19.

Legal (Occupation Code: 23–0000), $142.65.

The average hourly cost (salary plus benefits), weighting these skill sets evenly, is $100.50. We round it to $101/hour.

Frequency of Responses: One-time implementation (related to business procedures, capital/start-up).

Necessity of Information: In response to NAESB's standard development activities, the proposals in this NOPR would, if implemented, make minor adjustments to the standards previously adopted by the Commission. The standards consolidate the cybersecurity standards in one standards manual for ease of reference and revision, deleting one element in the Data Dictionary for Internet ET included in the WGQ Cybersecurity Related Standards and makes numerous minor changes throughout the corresponding manual and the WGQ QEDM Related Standards to correct typographical and capitalization errors.

39. Further, in response to industry requests or through the normal course of WGQ activities, the proposals in this NOPR would, if implemented, upgrade current business practices and communication standards by specifically: (1) adding a new data element, ''Cycle Indicator,'' to the data set for the Storage Information standard to address technical details for the reporting of storage balances and the activities that affect storage balances; (2) revising the data element ''Service Requester Contract'' contained in the data set for the Flowing Gas Related Allocation standard to identify the applicable contract and to support the communication of the results of processes used to allocate the actual flow of gas quantities to parties involved in a transaction; (3) modifying the ''Charge Type Rate'' data element contained in the data set for the Transportation/Sales Invoice standard that allows for the identification of multiple rates that may be applicable for a single transaction or service; and (4) adding a new sender's option data element, ''Location Indicator Data,'' to the Transactional Reporting—Capacity Release standard to improve efficiencies by providing a mechanism for a transportation service provider to communicate the locations at which a discounted rate is offered as well as if the rate is associated with a single location, multiple locations, or all locations. In addition, the Commission's Office of Enforcement will use the data for general industry oversight.

Internal Review: We have reviewed the requirements pertaining to business practices of interstate natural gas pipelines and made a preliminary determination that the proposed revisions are necessary to establish a more efficient and integrated pipeline network. These requirements conform to our plan for efficient information collection, communication, and management within the natural gas pipeline industries. We determined through our internal review that there is specific, objective support for the burden estimates associated with the information requirements.

40. Interested persons may obtain information on the reporting requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426 [email: *DataClearance@ferc.gov*].

41. Comments concerning the collection of information(s) and the associated burden estimate(s), should be sent to the Office of Information and Regulatory Affairs, the Office of Management and Budget, Washington, DC 20503 [Attention: Desk Officer for the Federal Energy Regulatory Commission, telephone: (202) 395–0710; fax: (202) 395–4718]. A copy of the comments on information collection should also be sent to the Commission, in Docket No. RM96–1–043 by any of the following methods:

- *eFiling at Commission's Website: http://www.ferc.gov/docs-filing/efiling.asp;*
- *U.S. Postal Service Mail:* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426; or
- Delivery of filings other than by eFiling or the U.S. Postal Service should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

VII. Environmental Analysis

42. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[27] The actions that we propose to take here fall within categorical exclusions in the Commission's regulations for rules that are clarifying, corrective, or procedural, for information gathering, analysis, and dissemination, and for rules regarding sales, exchange, and transportation of natural gas that require no construction of facilities.[28] Therefore, an environmental review is unnecessary and has not been prepared as part of this NOPR.

VIII. Regulatory Flexibility Act

43. The Regulatory Flexibility Act of 1980 (RFA) [29] generally requires a description and analysis of proposed rules that will have significant economic impact on a substantial number of small entities. The Commission is not required to make such an analysis if proposed regulations would not have such an effect.

44. Approximately 193 interstate natural gas pipelines, both large and small, are potential respondents subject to the requirements adopted by this rule. Most of the natural gas pipelines regulated by the Commission do not fall within the RFA's definition of a small entity,[30] which is currently defined for natural gas pipelines as a company that, in combination with its affiliates, has total annual receipts of $41.5 million or less.[31] For the year 2022, only 14 companies not affiliated with larger companies had annual revenues in combination with their affiliates of $41.5 million or less and therefore could be considered a small entity under the RFA. This represents about eight percent of the total universe of potential respondents that may have a significant burden imposed on them. We estimate that the one-time implementation cost of the proposals in this NOPR is $1,977,580 (or $10,247 per entity, regardless of entity size).[32] We do not consider the estimated $10,247 impact per entity to be significant. Moreover, these requirements are designed to benefit all customers, including small businesses that must comply with them. Further, as noted above, adoption of consensus standards helps ensure the reasonableness of the standards by requiring that the standards draw support from a broad spectrum of industry participants representing all segments of the industry. Because of that representation and the fact that industry conducts business under these standards, the Commission's regulations should reflect those standards that have the widest possible support.

45. Accordingly, pursuant to section 605(b) of the RFA,[33] the regulations

[27] *Reguls. Implementing the Nat'l Env't Pol'y Act,* Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs. ¶ 30,783 (1987) (cross-referenced at 41 FERC ¶ 61,284).

[28] *See* 18 CFR 380.4(a)(2)(ii), 380.4(a)(5), & 380.4(a)(27) (2023).

[29] 5 U.S.C. 601–612.

[30] *See* 5 U.S.C. 601(3) citing section 3 of the Small Business Act (SBA), 15 U.S.C. 623. Section 3 of the SBA defines a ''small business concern'' as a business that is independently owned and operated, and that is not dominant in its field of operation.

[31] 13 CFR 121.201 (Subsector 486-Pipeline Transportation; North American Industry Classification System code 486210; Pipeline Transportation of Natural Gas) (2023). ''Annual Receipts'' are total income plus cost of goods sold.

[32] This number is derived by dividing the total cost figure by the number of respondents. $1,977,580/193 = $10,247.

[33] 5 U.S.C. 605(b).

proposed herein should not have a significant economic impact on a substantial number of small entities.

IX. Comment Procedures

46. The Commission invites interested persons to submit comments on the matters and issues proposed in this notice to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due June 4, 2024. Comments must refer to Docket No. RM96–1–043, and must include the commenter's name, the organization they represent, if applicable, and their address in their comments. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

47. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's website at *https://www.ferc.gov/.* The Commission accepts most standard word processing formats. Documents created electronically using word processing software must be filed in native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

48. Commenters that are not able to file comments electronically may file an original of their comment by USPS mail or by courier-or other delivery services. For submission sent via USPS only, filings should be mailed to: Federal Energy Regulatory Commission, Office of the Secretary, 888 First Street NE, Washington, DC 20426. Submission of filings other than by USPS should be delivered to: Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

X. Document Availability

49. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*https://www.ferc.gov/*).

50. From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

51. User assistance is available for eLibrary and the Commission's website during normal business hours from the Commission's Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

List of Subjects in 18 CFR Part 284

Continental shelf, Incorporation by reference, Natural gas, Reporting and recordkeeping requirements.

By direction of the Commission.

Issued March 21, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

In consideration of the foregoing, the Commission proposes to amend Part 284, Chapter I, Title 18, Code of Federal Regulations, as follows.

PART 284—CERTAIN SALES AND TRANSPORTATION OF NATURAL GAS UNDER THE NATURAL GAS POLICY ACT OF 1978 AND RELATED AUTHORITIES

■ 1. The authority citation for part 284 continues to read as follows:

Authority: 15 U.S.C. 717–717z, 3301–3432; 42 U.S.C. 7101–7352; 43 U.S.C. 1331–1356.

■ 2. Amend § 284.12 by revising paragraph (a)(1) to read as follows:

§ 284.12 Standards for pipeline business operations and communications.

(a) * * *

(1) An interstate pipeline that transports gas under subparts B or G of this part must comply with the business practices and electronic communications standards as promulgated by the North American Energy Standards Board, as incorporated by reference in paragraphs (a)(1)(i) through (viii) of this section.

(i) Additional Standards (Version 4.0, September 29, 2023);

(ii) Nominations Related Standards (Version 4.0, September 29, 2023);

(iii) Flowing Gas Related Standards (Version 4.0, September 29, 2023);

(iv) Invoicing Related Standards (Version 4.0, September 29, 2023);

(v) Quadrant Electronic Delivery Mechanism Related Standards (Version 4.0, September 29, 2023);

(vi) Capacity Release Related Standards (Version 4.0, September 29, 2023); and

(vii) Internet Electronic Transport Related Standards (Version 4.0, September 29, 2023);

(viii) Cybersecurity Related Standards Manual (Version 4.0, September 29, 2023)

* * * * *

[FR Doc. 2024–06561 Filed 4–4–24; 8:45 am]

BILLING CODE 6717–01–P

Notices

Federal Register
Vol. 89, No. 67
Friday, April 5, 2024

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.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Information Collection Review Request for OMB Approval: BHA Workplace Culture Survey

AGENCY: U.S. Agency for International Development.

ACTION: Notice of information collection; request for comment.

SUMMARY: USAID's Bureau for Humanitarian Assistance (USAID/BHA) proposes to survey all members of its workforce to assess and gauge its processes for developing and improving a more cohesive BHA culture. This survey is also sent to institutional support contractors (ISCs), which are part of the USAID workforce but are members of the public for purposes of the Paperwork Reduction Act of 1995 (PRA). USAID/BHA invites the general public and other Federal agencies to take this opportunity to comment on the following new information collection as it relates to ISCs, as required by the PRA. 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.

DATES: 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.*

ADDRESSES: You may send comments (titled 'BHA Workforce Culture Survey Comments') by any of the following methods:

- *Email:* Kathryn Oberholzer at *koberholzer@usaid.gov.*
- *Mail:* Kathryn Oberholzer at Bureau for Humanitarian Assistance, 555 12th Street NW, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Kathryn Oberholzer, (571) 212–9899, *koberholzer@usaid.gov.*

SUPPLEMENTARY INFORMATION:

Type of Information Collection: BHA Workplace Culture Survey.

Type of Request: Notice for public comment.

Originating Office: USAID Bureau for Humanitarian Affairs.

Respondents: BHA personnel, including ISCs that are not federal employees for PRA purposes.

Respondent's Obligation to Respond: Voluntary.

Estimated Number of Respondents: 400.

Average Time per Response: 15 minutes for survey respondents.

Frequency of Response: Approximately once per year.

Total Estimated Burden: 100 hours.

Total Estimated Burden Cost: None.

We are soliciting public comments to permit USAID/BHA to include ISCs in its workforce survey to assess and gauge its processes for developing and improving a more cohesive BHA culture.

Danielle Mutone Smith,

Managing Director, Bureau for Humanitarian Assistance.

BHA Culture Survey Questions

****Privacy Act Statement****

Please see the Privacy Act Statement in its entirety in the ensuing section.

Introduction

As a part of the transformation of the Office of Foreign Disaster Assistance (OFDA) and Food For Peace (FFP) into BHA in 2020, we enlisted the support of USAID Staff Care organizational consultants to both assess the cultures of FFP and OFDA, and then engage staff in the design of a BHA culture that melds the best of both offices. To that end, BHA conducted a cultural assessment survey in March/April 2020, which has informed Staff Care's culture work with BHA offices and senior management. This culminated in a July 2021 workshop where office representatives integrated all the office-level work on culture into a BHA-wide culture document.*

In 2021 BHA conducted a second culture survey. This survey was implemented and analyzed by the Training Resources Group, Inc. (TRG) to ensure confidentiality of responses. TRG analyzed the data and shared results from the survey with BHA leadership and staff in early 2022. Subsequently, BHA Offices held meetings to focus on individual office results and action planning discussions.

The 2021 survey provides baseline data for our 2023 survey. This year's survey will allow us to gauge the process to date on developing a BHA culture.

Your participation is critical, so please note this survey is confidential. While we will be requesting demographic information so that we can analyze survey responses in a variety of ways, this information will not be attached to individuals who respond, and TRG consultants will be the only ones with access to the raw data.

(**Culture for the purposes of this survey means BHA's values, norms and behaviors that guide and inform BHA staff and how we work together.*)

(**Culture for the purposes of this survey means BHA's values, norms and behaviors that guide and inform BHA staff and how we work together.*)

Unit defined as: The immediate BHA team/office/group that you work closest with.

Bureau leadership defined as: BHA Front Office, Office directors based in Washington, DC.

Privacy Act Statement

In accordance with E.O. 14035: Executive Order on Diversity, Equity, Inclusion, and Accessibility in the Federal Workforce, we are collecting information relating to the culture of BHA and to the morale of all of our employees to help inform efforts to improve workplace culture.

BHA intends to use the voluntarily-given basic demographic information along with responses gauging morale and workplace culture at an aggregate level to examine where pain points in BHA's approach to work may be. With information about how employees of different genders, sexual identities, hiring mechanisms, disability statuses, and racial or ethnic groups feel about their unit and BHA's culture, office and bureau leadership will be better informed about how to focus and prioritize efforts related to culture change. Identifying how staff feel about their workplace culture and what factors are affecting their morale will allow

leaders at all levels in the bureau to create a better culture and improve conditions for groups where needed. The survey will be sent to staff at their USAID email address, the survey will indicate that staff will be asked for their consent to share demographic data, which they may decline to provide at their discretion. Staff will be notified about the purpose of the collection, what will be done with the information provided, and how the information will be retained and protected.

We will use this information to inform office and bureau-level follow up actions. Additionally, leaders at different levels in the bureau will be able to use the disaggregated data to inform their office culture improvement action plans. We plan to conduct annual cultural surveys to continue to track and invest in BHA culture change over time. Information will not be shared with any other entity or source, and will not be used for any other purpose beyond what is specified here.

In order to isolate the data from anyone who would have the ability to identify participants, our consultant partner, the Training Resources Group, Inc. (TRG), will execute, house, and disaggregate the data from this survey, protecting this information with the utmost integrity in accordance with their corporate privacy policies. No PII will be collected or shared. Two individuals in TRG will have access to the raw data only through two-factor authentication. Further, raw data will be deleted after one year after which a new culture survey will be disseminated to BHA staff.

Proposed Questions

Demographics

1. For which part of BHA do you work?
   a. Office of Field and Response Operations (FARO)
   b. Office of Humanitarian Business and Management Operations (HBMO)
   c. Office of Technical and Program Quality (TPQ)
   d. Office of Global Policy, Partnerships, Programs, and Communications (G3PC)
   e. Office of Asia, Latin America, and the Caribbean (ALAC)
   f. Office of Africa (OA)
   g. Office of Middle East, North Africa, and Europe (MENAE)
   h. Regional/country based
   i. Prefer Not to Respond
2. What is your hiring mechanism?
   a. U.S. Personal Services Contracts (USPSC)
   b. USPSC-Support Relief Group (USPSC–SRG)
   c. Third Country National Personal Services Contract (TCNPSC)
   d. Local Personal Services Contractor (Local PSC)
   e. Foreign Service National (FSN)
   f. Political Appointee
   g. Civil Service (CS)
   h. Foreign Service (FS)
   i. Foreign Service Limited (FSL)
   j. Civil Service Excepted (CSE)
   k. Participating Agency Service Agreement (PASA)
   l. Participating Agency Service Agreement Detailer (PASA Detailer)
   m. Institutional Contractor
   n. Fellow
   o. Intern
   p. Other
   q. Prefer Not to Respond
3. How long have you been with BHA (including OFDA/FFP time)?
   a. 0–1 year
   b. 1–3 years
   c. 4–7 years
   d. 8–15 years
   e. 15+ years
4. With which racial and ethnic group(s) do you identify? Please mark all that apply.
   a. Native American or Alaska Native
   b. East Asian, South Asian, Southeast Asian
   c. North African/Middle Eastern
   d. African
   e. Black or African American
   f. Hispanix or Latinx
   g. White
   h. Native Hawaiian or other Pacific Islander
   i. Other
   j. Prefer Not to Respond
5. Do you identify as a gender or sexual minority?
   a. Yes, I identify as a gender or sexual minority.
   b. No, I do not identify as a gender or sexual minority.
   c. Prefer Not to Respond
6. How do you describe your disability/ability status? Please mark all that apply.
   a. Yes, I have a disability for which I have sought a reasonable accommodation.
   b. Yes, I have a disability for which I have NOT sought a reasonable accommodation.
   c. No, I do not have a disability.
   d. I prefer not to respond.
7. Do you lead, manage or supervise other members of the BHA workforce?
   a. Yes
   b. No

Workplace Culture (Values/Norms/Behaviors)

8. I feel my workplace values are aligned with BHA values?
   a. Totally Disagree, Somewhat Disagree, Neutral, Somewhat Agree, Totally Agree, No opinion (same scale for 10–20)
9. I feel that my teammates trust me.
10. I trust my teammates.
11. I feel valued by those in my unit.
12. I value my unit members.
13. (OPTIONAL) My US/Field counterpart respects my input and opinions.
   a. Optional, if applicable
14. I feel I can disclose a suspected misconduct, violation of any law, rule or regulation without fear of reprisal.
15. What do you most value about BHA culture? (500 characters)

Leadership

16. Unit leadership listens to and respects me/my work.
17. I feel that a workforce of all cultures and backgrounds are made to feel included and valued in BHA.
18. Bureau leadership and/or regional office leads create opportunities for all voices and perspectives to be heard and valued in an environment of trust.
19. I feel Bureau and unit leadership clearly communicate their decisions.
20. I feel unit leadership advances DEIA and other efforts to improve culture.

Morale

21. My work morale is:
   a. Very Low, Low, Somewhat Low, Neutral, Somewhat High, Very High
22. The morale of my unit is:
   a. Very Low, Low, Somewhat Low, Neutral, Somewhat High, Very High
23. The morale of BHA is:
   a. Very Low, Low, Somewhat Low, Neutral, Somewhat High, Very High
24. I am comfortable (check all that apply):
   a. Using workplace flexible options if available to you.
   b. Signing off at a regular hour.
   c. Taking time off from work.
   d. Not responding to emails during off hours, unless urgent.
25. What four factors impact your morale the most (check all that apply)?
   a. USAID plans for returning to the office
   b. Prioritization of work
   c. Amount of work
   d. Issues around DEIA
   e. Issues around Harassment, Sexual Harassment, and Bullying
   f. Management Issues (transparency, accessibility, changes in)
   g. Interpersonal relationships with my colleagues
   h. Issues around systems/processes

i. Ability to fully express my ideas and thoughts about work
j. Support and empowerment in advancing my career
k. Personal Issues
l. Other (50 characters)

26. If you selected ''Other'' to the previous question, please provide your description here.

Final Comments

1. Where should leadership focus its attention over the next year to continue to build culture? (500 characters)

[FR Doc. 2024–07240 Filed 4–4–24; 8:45 am]

BILLING CODE 6116–01–P

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Commodity Credit Corporation

Notice of Request for Revision of Currently Approved Information Collection

AGENCY: Foreign Agricultural Service, Commodity Credit Corporation, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Foreign Agricultural Service's (FAS) intention and Commodity Credit Corporation's (CCC) intention to request on behalf of the Commodity Credit Corporation (CCC) a revision from the Office of Management and Budget (OMB) for a currently approved information collection process in support of the USDA's Regional Agricultural Promotion Program.

DATES: Comments on this notice must be received by June 4, 2024 to be assured of consideration.

ADDRESSES: You may send comments, identified by OMB Control Number 0551–0049, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* This portal enables respondents to enter short comments or attach a file containing lengthier comments.
- *Email: PODadmin@usda.gov.* Include OMB Control Number 0551–0049 in the subject line of the message.
- *Mail, Courier, or Hand Delivery:* Curt Alt, U.S. Department of Agriculture, Foreign Agricultural Service, 1400 Independence Avenue SW, Room 6512, Washington, DC 20250.

Instructions: All submissions received must include the agency names and OMB Control Number for this notice. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Curt Alt, 202 690–4784, *Podadmin@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Regional Agricultural Promotion Program.

OMB Number: 0551–0049.

Expiration Date of Approval: August 31, 2025.

Type of Request: Revision of a currently approved information collection.

Abstract: Under the Regional Agricultural Promotion Program (RAPP), information will be gathered from applicants to the program and from existing program participants that have been approved to conduct market promotion activities that promote U.S. agricultural commodities in foreign markets, including activities that address existing or potential non-tariff barriers to trade. The information collected will be used primarily by FAS to manage, plan, evaluate, and account for government resources. This revision is necessary to update the burden estimate to account for new applications being received under RAPP.

Estimate of Burden: The public reporting burden for each respondent resulting from information collected under the RAPP varies in direct relation to the number and type of agreements entered into by such respondents. The estimated average reporting burden for the RAPP is 16 hours per response.

Type of Respondents: Nonprofit U.S. agricultural trade organizations, nonprofit state regional trade groups, U.S. agricultural cooperatives, and state agencies.

Estimated Number of Respondents: 70 per annum.

Estimated Number of Responses per Respondent: 55 per annum.

Estimated Total Annual Burden of Respondents: 55,029 hours.

Copies of this information collection can be obtained from Dacia Rogers, the Agency Information Collection Coordinator, at *Dacia.Rogers@usda.gov.*

Request for Comments: Send comments regarding (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information including validity of the methodology and assumption used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be available without change, including any personal information provided, for inspection online at *https://www.regulations.gov* and at the mail address listed above between 8:00 a.m. and 4:30 p.m., Monday through Friday, except holidays.

Comments will be summarized and included in the submission for OMB approval.

Persons with disabilities who require an alternative means for communication of information (Braille, large print, audiotape, etc.) should contact *RARequest@usda.gov.*

Zach Ducheneaux,

Executive Vice President, Commodity Credit Corporation.

Daniel Whitley,

Administrator, Foreign Agricultural Service.

[FR Doc. 2024–07204 Filed 4–4–24; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

[Docket No. NRCS–2024–0002]

Notice of Intent To Prepare an Environmental Impact Statement for the Clarke County Water Supply Project, Clarke County, Iowa

AGENCY: Natural Resources Conservation Service, USDA.

ACTION: Notice of Intent (NOI) to prepare an Environmental Impact Statement (EIS).

SUMMARY: The Natural Resources Conservation Service (NRCS) Iowa State Office announces its intent to prepare a watershed plan for the Clarke County Water Supply project, which is located approximately 27.2 miles upstream of the confluence with the South River in the proximity of Osceola, Iowa. The proposed watershed plan will examine alternative solutions to the limited availability of a reliable water supply. The Clarke County Water Supply project includes the cities of Osceola, Murray, and Woodburn, Iowa, and the Clarke

County rural service area. NRCS is requesting comments to identify significant issues, potential alternatives, information, and analyses relevant to the proposed action from all interested individuals, Federal and State agencies, and Tribes.

DATES: We will consider comments that we receive by May 6, 2024. We will consider comments received after close of the comment period to the extent possible.

ADDRESSES: We invite you to submit comments in response to this notice. You may submit your comments through one of the methods below:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and search for docket ID NRCS–2024–0002. Follow the online instructions for submitting comments; or
- *Mail or Hand Delivery:* Jon Hubbert, State Conservationist, Natural Resources Conservation Service, 210 Walnut Street Room 693, Des Moines, IA 50309. In your comments, specify the docket ID NRCS–2024–0002.

All comments received will be posted without change and made publicly available on *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jon Hubbert; telephone: (515) 284–4769; email: *jon.hubbert@usda.gov.* Individuals who require alternative means for communication should contact the U.S. Department of Agriculture (USDA) Target Center at (202) 720–2600 (voice and text telephone (TTY)) or dial 711 for Telecommunications Relay service (both voice and text telephone users can initiate this call from any telephone).

SUPPLEMENTARY INFORMATION:

Purpose and Need

The primary purpose of the watershed plan is to provide a reliable drinking water supply to meet current and future demands in Clarke County, Iowa. Watershed planning is authorized under the Watershed Protection and Flood Prevention Act of 1954 (Pub. L. 83–566), as amended, and the Flood Control Act of 1944 (Pub. L. 78–534). The sponsoring local organization (SLO) is the Clarke County Reservoir Commission (CCRC) whose members are the cities of Osceola, Murray, and Woodburn, Iowa; Clarke County, Iowa; Osceola Water Works Board of Trustees; and Southern Iowa Rural Water Association (SIRWA).

The study area includes all of Clarke County where the water supply is provided by the existing West Lake Reservoir. Osceola Water Works treats raw water from West Lake, which is the sole water supply source reservoir. SIRWA purchases potable water from Osceola Water Works and distributes it to other users in Clarke County.

This action is needed to address deficiencies in the agricultural water delivery system, which are having negative impacts on current public health and economic growth. Limited water supply can impact public health and safety due to the lack of safe drinking water and the lack of water supply for other public needs, such as firefighting. Quality of life for residents is impacted due to the potential for water use restrictions during droughts. Economic growth has been limited in the area because the supply is too limited to support new businesses. Additionally, future water demands are anticipated to grow, and the current supply will be increasingly insufficient.

The reservoir at West Lake has insufficient storage during moderate to severe droughts. The reservoir has gone through substantial draw down during four drought periods over the last 40 years requiring various degrees of water restrictions. West Lake is in its third year with lake levels below the spillway and Clarke County remains in a moderate to severe drought. The remaining water supply in West Lake was estimated to be less than a year in October 2023. The water conservation ordinance has been increased to Section 3—Water Emergency.

To meet the purpose of agricultural water supply for the Clarke County service area, a safe and reliable water supply with an average daily capacity of 2.0 million gallons per day is being requested. There is a long history of water supply investigations in Clarke County. The city of Osceola commissioned a study by an engineering firm in 1990 to evaluate West Lake. The result of the study showed that West Lake would not meet the projected water supply demand. At the request of local officials, USDA Soil Conservation Service conducted a study of six potential sites and published the results in a report titled, ''Reconnaissance Report: Potential Water Supply Reservoirs, City of Osceola and Rural Users, Clarke County, Iowa'' (1991). Local sponsors made requests for PL–566 planning assistance in 1992 and 1996, however funding for pre-authorization planning activities was not available on either occasion. Two other studies, one in 1996 and the other in 1999, were conducted evaluating alternative water supply sources and the potential for increasing yield from West Lake. In 2002, the Osceola Water Board of Trustees, rural users, and other sponsoring bodies organized and formed a 28E organization to become the CCRC. The CCRC requested planning assistance from NRCS in 2003 which was authorized late in 2004.

Estimated federal funds required for the construction of the proposed action may exceed $25 million and the proposed action will, therefore, require congressional approval per the Consolidated Appropriations Act, 2018 amended funding threshold. In accordance with the regulation in 7 CFR 650.7(a)(2), an EIS is required for projects requiring congressional approval.

Preliminary Proposed Action and Alternatives

The EIS objective is to formulate and evaluate alternatives for the agricultural water supply in the Clarke County service area. The EIS is expected to evaluate three alternatives: two action alternatives, and one no action alternative. The alternatives that may be considered for detailed analysis include:

- *Alternative 1—Proposed Action—Water Supply Reservoir:* The proposed action is to evaluate a water supply reservoir developed with a dam at site 4B, which would include an earthfill embankment dam with reinforced concrete pressure pipe spillway and vegetated auxiliary spillway. The proposed project would also include a 6-mile water supply pipeline to transport water from the reservoir to the water treatment plant. The dam construction and inundated area would require the relocation of a segment of a local road (Truro Pavement). The normal pool (at 1001 foot elevation) would inundate 790 acres. The maximum height of the dam would be 58 feet. The reservoir has 11,030 acre-feet of storage and a design withdrawal capacity of 2.0 million gallons per day on an average daily basis during drought conditions, which would meet the need of the project.
- *Alternative 2—Proposed Action—Single Purpose Water Supply Pipeline:* The proposed action would evaluate purchasing water from Des Moines Water Works. This alternative would require a one-time construction cost to install of 20-inch diameter pipeline 38.5 miles long from the Des Moines Waterworks to the City of Osceola, and a booster station in between. A buy-in fee would be part of the start-up cost for service. Monthly rates and fees for treated water use would apply over the life of the project. The proposed action would be able to provide 2.0 million gallons per day on an average daily basis during drought conditions which would meet the need of the project.

• *Alternative 3—No Action Alternative:* Taking no action would consist of activities conducted if no federal action or funding were provided. If the No Action Alternative is selected water supply limitations would continue to impact residents of Clarke County quality of life, public health and safety, and future economic growth. No federal action or funding would be associated with the No Action Alternative.

Summary of Expected Impacts

As mentioned above, the estimated Federal contribution to construction cost will exceed $25 million. The EIS will be prepared as required by section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA); the Council on Environmental Quality Regulations (40 CFR parts 1500–1508); and NRCS regulations that implement NEPA in 7 CFR part 650.

CCRC and NRCS evaluated the current relevant project conditions with early scoping and a preliminary conceptual design, which indicates that the proposed alternatives may have local, regional, or national impacts on the environment. The impacts may include: dam structure and inundation from the reservoir; temporary and adverse impacts from construction activities; and permanent beneficial impacts from adequate drinking water supply. NRCS will coordinate with the appropriate federal agencies throughout the planning process to minimize impacts, and consider mitigation.

Potential effects include the following:

- soils;
- prime and unique farmland;
- land use;
- water resources, including wetlands, streams, and water quality;
- floodplains;
- terrestrial and aquatic wildlife, including threatened and endangered species and those included under the Migratory Bird Treaty Act;
- cultural resources and historic properties;
- public health, safety, and transportation; and
- social and economic conditions.

Long-term beneficial effects would occur with an increase in agricultural water supply.

Anticipated Permits and Authorizations

The following permits and authorizations are anticipated to be required:

• *Clean Water Act (CWA) and National Pollutant Discharge Elimination System (NPDES).* The project would require water quality certification under Section 401 of the CWA, permitting under Section 402 of the NPDES, and Section 404 of the CWA for potential wetland impacts.

• *Endangered Species Act Section 7.* NRCS and CCRC are currently developing a Biological Assessment (BA) to support ESA Section 7 consultation with the U.S. Fish and Wildlife Service.

• *National Historic Preservation Act (NHPA) Section 106.* Consultation with Tribal Nations and interested parties would be conducted as required by the NHPA.

• *National Flood Insurance Program.* A Letter of Map Revision/Conditional Letter of Map Revision would be required from the Federal Emergency Management Agency.

• *Dam Safety and Floodplain Permit.* Local dam safety and floodplain permits will be required for construction and operation of the dam from the Iowa Department of Natural Resources (IDNR) as required in Iowa Administrative Code (IAC) 567.

• *IAC, Environmental Protection Commission 567, Chapter 43, Water Supplies—Design and Operation.* Water Supply Storage, Water Use, and Construction Permits must be obtained from IDNR Water Supply Engineering Section for the Reservoir, Intake and Pipeline. Requirements must be met for the Water Allocation and Use program, including a Water Use Permit. Construction standards for public water supplies must be met as set forth under IAC 567, Chapter 43.

• *Review and acceptance of Final Engineering Plans and Specifications.* The final design and construction drawings and specifications must be reviewed and approved by IDNR and NRCS prior to implementation. Using the NRCS National Operation and Maintenance Manual (O&M), an O&M plan will be prepared.

• *Development—Conditional Use Permit, Grading Permit, Utility Permit, and Entrance Permit.* These are all local permits that must be obtained from Clarke County.

Schedule of Decision-Making Process

A Draft EIS (DEIS) will be prepared and circulated for review and comment by agencies, Tribes, consulting parties, and the public for 45 days as required by the regulations in 40 CFR 1503.1, 1502.20, 1506.11, and 1502.17, and 7 CFR 650.13. The DEIS is anticipated to be published in the **Federal Register**, approximately 6 months after publication of this NOI. A Final EIS is anticipated to be published within 6 months of completion of the public comment period for the DEIS.

NRCS will decide whether to implement one of the action alternatives as evaluated in the EIS. A Record of Decision will be completed after the required 30-day waiting period and will be publicly available. The responsible Federal official and decision maker for the NRCS is the Iowa NRCS State Conservationist.

Public Scoping Process

A public scoping meeting was held on August 19, 2021. Comments received, including the names and addresses of those who commented, were part of the public record. Scoping meeting presentation materials were available for review and comment for 30 days from Thursday, August 19, 2021, through Saturday, September 18, 2021.

Federal, State, Tribal, local agencies and representatives, and the public were invited to take part in the watershed plan scoping period through which coordination sought input on issues of economic, environmental, cultural, and social importance in the watershed. CCRC and NRCS organized the public scoping meeting to provide an opportunity to review and evaluate the project alternatives, express concern or support, and gain further information regarding the project. To determine the most viable alternatives to carry forward to the EIS, the CCRC used input obtained during public scoping discussions to focus on relevant resource concerns and issues and eliminated those that were not relevant from further detailed study.

Identification of Potential Alternatives, Information, and Analyses

NRCS invites agencies, Tribes, consulting parties, and individuals who have special expertise, legal jurisdiction, or interest in the Clarke County Water Supply project to provide comments concerning the scope of the analysis and identification of potential alternatives, information, and analyses relevant to the Proposed Action.

NRCS will coordinate the scoping process to correspond with any required NHPA processes, as allowed in the regulations in 36 CFR 800.2(d)(3) and 800.8 (54 U.S.C. 306108). The information about historic and cultural resources within the area potentially affected by the proposed project will assist NRCS in identifying and evaluating impacts to such resources in the context of both NEPA and NHPA.

NRCS will consult with Native American tribes on a government-to-government basis in accordance with the regulations in 36 CFR 800.2 and 800.3, Executive Order 13175, and other policies. Tribal concerns, including

impacts on Indian trust assets and potential impacts to cultural resources and historic properties, will be given due consideration.

Authorities

This document is published as specified by the NEPA regulations regarding publication of an NOI to issue an EIS (40 CFR 1501.9(d)). Watershed planning is authorized under the Watershed Protection and Flood Prevention Act of 1954, as amended, and the Flood Control Act of 1944.

Federal Assistance Programs

The title and number of the Federal Assistance Program as found in the Assistance Listing [1] to which this document applies is 10.904, Watershed Protection and Flood Prevention.

Executive Order 12372

Executive Order 12372, ''Intergovernmental Review of Federal Programs,'' requires consultation with State and local officials that would be directly affected by proposed Federal financial assistance. The objectives of the Executive order are to foster an intergovernmental partnership and a strengthened federalism, by relying on State and local processes for State and local government coordination and review of proposed Federal financial assistance and direct Federal development. This project is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

USDA Non-Discrimination Policy

In accordance with Federal civil rights law and USDA civil rights regulations and policies, USDA, its agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family or parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Individuals who require alternative means of communication for program information (for example, braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or the USDA TARGET Center at (202) 720–2600 (voice and telephone) or dial 711 for Telecommunications Relay Service (both voice and text telephone users can initiate this call from any phone). Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at: *https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint* and at any USDA office or write a letter addressed to USDA and provide in the letter all the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by: (1) mail to: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; (2) fax: (202) 690–7442; or (3) email: *program.intake@usda.gov.*

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Jon Hubbert,

Iowa State Conservationist, Natural Resources Conservation Service.

[FR Doc. 2024–07291 Filed 4–4–24; 8:45 am]

BILLING CODE 3410–16–P

[1] See *https://sam.gov/content/assistance-listings.*

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Puerto Rico Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a meeting of the Puerto Rico Advisory Committee to the Commission will convene by virtual web conference on Wednesday, April 24, 2024, at 3:30 p.m. Atlantic Time/ Eastern Time. The purpose is to continue discussion on their project on the civil rights impacts of the Insular Cases in Puerto Rico.

DATES: April 24, 2024, Wednesday, at 3:30 p.m. Atlantic Time (3:30 p.m. ET).

ADDRESSES: Meeting will be held via Zoom.

Registration Link (Audio/Visual): http://tinyurl.com/bdvhsw2h; Passcode, if needed: USCCR–PR.

Join by Phone (Audio Only): 1–833 435 1820 USA Toll Free; Meeting ID: 161 817 5885#.

FOR FURTHER INFORMATION CONTACT: Email Victoria Moreno, Designated Federal Officer at *vmoreno@usccr.gov,* or by phone at 434–515–0204.

SUPPLEMENTARY INFORMATION: This meeting will take place in Spanish with English interpretation. This committee meeting is available to the public through the registration link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Per the Federal Advisory Committee Act, public minutes of the meeting will include a list of persons who are present at the meeting. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Closed captioning will be available for individuals who are deaf, hard of hearing, or who have certain cognitive or learning impairments. To request additional accommodations, please email *ebohor@usccr.gov* at least 10 business days prior to the meeting.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Victoria Moreno at *vmoreno@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at 1–312–353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meetings will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Puerto Rico Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Coordination Unit at *ebohor@usccr.gov.*

Agenda

1. Welcome & Roll Call
2. Committee Discussion on Project Regarding the Civil Rights Impacts of the Insular Cases in Puerto Rico
3. Next Steps
4. Public Comment
5. Other Business
6. Adjourn

Dated: April 1, 2024.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2024–07201 Filed 4–4–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Order Renewing Temporary Denial of Export Privileges

Aviastar—TU, 5 b. 7 Leningradsky prospekt, g. Moskva, 125040, Moscow, Russia

Pursuant to section 766.24 of the Export Administration Regulations, 15 CFR parts 730–774 (''EAR'' or ''the Regulations''),[1] I hereby grant the request of the Office of Export Enforcement (''OEE'') to renew the temporary denial order (''TDO'') issued in this matter on April 14, 2023. I find that renewal of this order is necessary in the public interest to prevent an imminent violation of the Regulations and that renewal for an extended period is appropriate because Aviastar—TU's (''Aviastar'') has engaged in a pattern of repeated, ongoing and/or continuous apparent violations of the EAR.

I. Procedural History

On April 21, 2022, I signed an order denying Aviastar export privileges for a period of 180 days on the ground that issuance of the order was necessary in the public interest to prevent an imminent violation of the Regulations. The order was issued *ex parte* pursuant to Section 766.24(a) of the Regulations and was effective upon issuance.[2] The temporary denial order was subsequently renewed on October 17, 2022,[3] April 14, 2023,[4] and October 6, 2023 [5] in accordance with section 766.24(d) of the Regulations.[6]

On March 11, 2024, BIS, through OEE, submitted a written request for a fourth renewal of the TDO. The written request was made more than 20 days before the TDO's scheduled expiration and, given the temporary suspension of international mail service to Russia, OEE has attempted to deliver a copy of the renewal request to Aviastar by alternative means in accordance with sections 766.5 and 766.24(d) of the Regulations. No opposition to the renewal of the TDO has been received.

II. Renewal of the TDO

A. Legal Standard

Pursuant to Section 766.24, BIS may issue an order temporarily denying a respondent's export privileges upon a showing that the order is necessary in the public interest to prevent an ''imminent violation'' of the Regulations, or any order, license or authorization issued thereunder. 15 CFR 766.24(b)(1) and 766.24(d). ''A violation may be 'imminent' either in time or degree of likelihood.'' 15 CFR 766.24(b)(3). BIS may show ''either that a violation is about to occur, or that the general circumstances of the matter under investigation or case under criminal or administrative charges demonstrate a likelihood of future violations.'' *Id.* As to the likelihood of future violations, BIS may show that the violation under investigation or charge ''is significant, deliberate, covert and/or likely to occur again, rather than technical or negligent[.]'' *Id.* A ''lack of information establishing the precise time a violation may occur does not preclude a finding that a violation is imminent, so long as there is sufficient reason to believe the likelihood of a violation.'' *Id.*

If BIS believes that renewal of a denial order is necessary in the public interest to prevent an imminent violation, it may file a written request for renewal, with any modifications if appropriate. 15 CFR 766.24(d)(1). The written request, which must be filed no later than 20 days prior to the TDO's expiration, should set forth the basis for BIS's belief that renewal is necessary, including any additional or changed circumstances. *Id.* ''In cases demonstrating a pattern of repeated, ongoing and/or continuous apparent violations, BIS may request the renewal of a temporary denial order for an additional period not exceeding one year.'' [7] *Id.*

B. The TDO and BIS's Request for Renewal

The U.S. Commerce Department, through BIS, responded to the Russian Federation's (''Russia's'') further invasion of Ukraine by implementing a sweeping series of stringent export controls that severely restrict Russia's access to technologies and other items that it needs to sustain its aggressive military capabilities. These controls primarily target Russia's defense, aerospace, and maritime sectors and are intended to cut off Russia's access to vital technological inputs, atrophy key sectors of its industrial base, and undercut Russia's strategic ambitions to exert influence on the world stage. Effective February 24, 2022, BIS imposed expansive controls on aviation-related (*e.g.,* Commerce Control List Categories 7 and 9) items to Russia, including a license requirement for the export, reexport or transfer (in-country) to Russia of any aircraft or aircraft parts specified in Export Control Classification Number (''ECCN'') 9A991 (section 746.8(a)(1) of the EAR).[8] BIS will review any export or reexport license applications for such items under a policy of denial. *See* section 746.8(b). Effective March 2, 2022, BIS excluded any aircraft registered in, owned, or controlled by, or under charter or lease by Russia or a national of Russia from being eligible for license exception Aircraft, Vessels, and Spacecraft (''AVS'') (Section 740.15 of the EAR).[9] Accordingly, any U.S.-origin aircraft or foreign aircraft that includes more than 25% controlled U.S.-origin content, and that is registered in, owned, or controlled by, or under charter or lease by Russia or a national of Russia, is subject to a license

[1] On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which includes the Export Control Reform Act of 2018, 50 U.S.C. 4801–4852 (''ECRA''). While section 1766 of ECRA repeals the provisions of the Export Administration Act, 50 U.S.C. App. 2401 *et seq.* (''EAA''), (except for three sections which are inapplicable here), section 1768 of ECRA provides, in pertinent part, that all orders, rules, regulations, and other forms of administrative action that were made or issued under the EAA, including as continued in effect pursuant to the International Emergency Economic Powers Act, 50 U.S.C. 1701 *et seq.* (''IEEPA''), and were in effect as of ECRA's date of enactment (August 13, 2018), shall continue in effect according to their terms until modified, superseded, set aside, or revoked through action undertaken pursuant to the authority provided under ECRA. Moreover, section 1761(a)(5) of ECRA authorizes the issuance of temporary denial orders. 50 U.S.C. 4820(a)(5).

[2] The TDO was published in the **Federal Register** on April 26, 2022 (87 FR 24514).

[3] The October 17, 2022 renewal order, which was effective upon issuance, was published in the **Federal Register** on October 20, 2022 (87 FR 63760).

[4] The April 14, 2023 renewal order, which was also effective upon issuance, was published in the **Federal Register** on April 19, 2023 (88 FR 24162).

[5] The October 6, 2023 renewal order, which was effective upon issuance, was published in the **Federal Register** on October 13, 2023 (88 FR 70928).

[6] Section 766.24(d) provides that BIS may seek renewal of a temporary denial order for additional 180-day renewal periods, if it believes that renewal is necessary in the public interest to prevent an imminent violation. Renewal requests are to be made in writing no later than 20 days before the scheduled expiration date of a temporary denial order.

[7] 88 FR 59791 (Aug. 30, 2023).

[8] 87 FR 12226 (Mar. 3, 2022). Additionally, BIS published a final rule effective April 8, 2022, which imposed licensing requirements on items controlled on the Commerce Control List (''CCL'') under Categories 0–2 that are destined for Russia or Belarus. Accordingly, now all CCL items require export, reexport, and transfer (in-country) licenses if destined for or within Russia or Belarus. 87 FR 22130 (Apr. 14, 2022).

[9] 87 FR 13048 (Mar. 8, 2022).

requirement before it can travel to Russia.

OEE's request for renewal for a period of one year is based upon the facts underlying the issuance of the TDO and the renewal orders subsequently issued in this matter on October 17, 2022, April 14, 2023, and October 6, 2023, as well as other evidence developed during this investigation. This evidence demonstrates that Aviastar has continued, and continues, to act in blatant disregard for U.S. export controls and the terms of previously issued TDOs. Specifically, the initial TDO, issued on April 21, 2022, was based on evidence that Aviastar engaged in conduct prohibited by the Regulations by operating multiple aircraft subject to the EAR and classified under ECCN 9A991.b on flights into Russia after March 2, 2022, from destinations including, but not limited to, Hangzhou, China; Shenzhen, China; and Zhengzhou, China from/to Novosibirsk, Russia and Abakan, Russia, without the required BIS authorization.[10] Further evidence indicated that Aviastar also operated aircraft subject to the EAR on domestic flights within Russia, potentially in violation of Section 736.2(b)(10) of the Regulations.

As discussed in the prior renewal orders, BIS presented evidence indicating that, after the initial April 21, 2022 TDO issued, Aviastar continued to operate aircraft subject to the EAR and classified under ECCN 9A991.b on flights both into and within Russia, in violation of the Regulations and the TDO itself.[11] The October 17, 2022 order detailed flights into and out of Russia from/to Hangzhou, China and Zhengzhou, China.[12] The April 14, 2023 and October 6, 2023 orders detailed domestic flights within Russia.[13]

Since that time, Aviastar continued to engage in conduct prohibited by the TDO and Regulations. In its March 11, 2024 request for TDO renewal, BIS submitted evidence that Aviastar continues to operate aircraft subject to the EAR and classified under ECCN 9A991.b, both on flights into and within Russia, in violation of the October 6, 2023 renewal order and/or the Regulations. Specifically, BIS's evidence and related investigation demonstrates that Aviastar continued to operate aircraft subject to the EAR, including, but not limited to, on flights into and out of Russia from/to Hangzhou, China as well as domestically within Russia. Information about those flights includes, but is not limited to, the following:

Tail No.	Serial No.	Aircraft type	Departure/arrival cities	Dates
RA–73351	25696	757–223 (PCF) (B752)	Yuzhno-Sakhalinsk, RU/Moscow, RU	March 15, 2024.
RA–73351	25696	757–223 (PCF) (B752)	Norilsk, RU/Moscow, RU	March 5, 2024.
RA–73351	25696	757–223 (PCF) (B752)	Hangzhou, CN/Novosibirsk, RU	March 3, 2024.
RA–73351	25696	757–223 (PCF) (B752)	Nizhnevartovsk, RU/Yakutsk, RU	February 12, 2024.
RA–73351	25696	757–223 (PCF) (B752)	Mirny, RU/Krasnoyarsk, RU	February 6, 2024.
RA–73354	27053	757–223 (PCF) (B752)	Norilsk, RU/Moscow, RU	March 18, 2024.
RA–73354	27053	757–223 (PCF) (B752)	Novosibrisk, RU/Moscow, RU	March 6, 2024.
RA–73354	27053	757–223 (PCF) (B752)	Moscow, RU/Norilsk, RU	March 1, 2024.
RA–73354	27053	757–223 (PCF) (B752)	Mirny, RU/Ulan-Ude, RU	February 9, 2024.
RA–73354	27053	757–223 (PCF) (B752)	Blagoveshchensk, RU/Moscow, RU	December 27, 2023.

III. Findings

Under the applicable standard set forth in section 766.24 of the Regulations and my review of the entire record, I find that the evidence presented by BIS convincingly demonstrates that Aviastar has acted in violation of the Regulations and the TDO; that such violations have been significant and deliberate; and that given the foregoing and the nature of the matters under investigation, there is a likelihood of imminent violations. Therefore, renewal of the TDO is necessary in the public interest to prevent imminent violation of the Regulations and to give notice to companies and individuals in the United States and abroad that they should avoid dealing with Aviastar, in connection with export and reexport transactions involving items subject to the Regulations and in connection with any other activity subject to the Regulations.

IV. Order

It is therefore ordered:

First, Aviastar—TU, 5 b. 7 Leningradsky prospekt, g. Moskva, 125040, Moscow, Russia, when acting for or on their behalf, any successors or assigns, agents, or employees may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the EAR, or in any other activity subject to the EAR including, but not limited to:

A. Applying for, obtaining, or using any license (except directly related to safety of flight), license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations, or engaging in any other activity subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or from any other activity subject to the EAR except directly related to safety of flight and

[10] Publicly available flight tracking information shows that on April 10, 2022, serial number (SN) 27054 flew from Hangzhou, China to Novosibirsk, Russia, and on April 12, 2022, SN 27054 flew from Zhengzhou, China to Abakan, Russia. In addition, on April 12, 2022, SN 27053 flew from Shenzhen, China to Abakan, Russia.

[11] Engaging in conduct prohibited by a denial order violates the Regulations. 15 CFR 764.2(a) and (k).

[12] Publicly available flight tracking information shows that on May 22, 2022, SN 27054 flew from Zhengzhou, China to Novosibirsk, Russia, and on May 25, 2022, SN 27053 flew from Hangzhou, China to Novosibirsk, Russia. In addition, on September 22, 2022, SN 25731 flew from Irkutsk, Russia to Moscow, Russia.

[13] Publicly available flight tracking information shows that on February 24, 2023, SN 27053 flew from Novosibirsk, Russia to Mirny, Russia. On March 7, 2023, SN 25696 flew from Novosibirsk, Russia to Moscow, Russia. On September 26, 2023 SN 25731 flew from Ulan-Ude, Russia to Moscow, Russia. In addition, SN 27054 flew from Norilsk, Russia to Moscow, Russia.

authorized by BIS pursuant to section 764.3(a)(2) of the Regulations.

Second, that no person may, directly or indirectly, do any of the following:

A. Export, reexport, or transfer (in-country) to or on behalf of Aviastar any item subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by Aviastar of the ownership, possession, or control of any item subject to the EAR that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby Aviastar acquires or attempts to acquire such ownership, possession or control except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from Aviastar of any item subject to the EAR that has been exported from the United States except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations;

D. Obtain from Aviastar in the United States any item subject to the EAR with knowledge or reason to know that the item will be, or is intended to be, exported from the United States except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations; or

E. Engage in any transaction to service any item subject to the EAR that has been or will be exported from the United States and which is owned, possessed or controlled by Aviastar, or service any item, of whatever origin, that is owned, possessed or controlled by Aviastar if such service involves the use of any item subject to the EAR that has been or will be exported from the United States except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations. For purposes of this paragraph, servicing means installation, maintenance, repair, modification, or testing.

Third, that, after notice and opportunity for comment as provided in section 766.23 of the EAR, any other person, firm, corporation, or business organization related to Aviastar by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order.

In accordance with the provisions of sections 766.24(e) of the EAR, Aviastar may, at any time, appeal this Order by filing a full written statement in support of the appeal with the Office of the Administrative Law Judge, U.S. Coast Guard ALJ Docketing Center, 40 South Gay Street, Baltimore, Maryland 21202–4022.

In accordance with the provisions of section 766.24(d) of the EAR, BIS may seek renewal of this Order by filing a written request not later than 20 days before the expiration date. A renewal request may be opposed by Aviastar as provided in section 766.24(d), by filing a written submission with the Assistant Secretary of Commerce for Export Enforcement, which must be received not later than seven days before the expiration date of the Order.

A copy of this Order shall be provided to Aviastar, and shall be published in the **Federal Register**.

This Order is effective immediately and shall remain in effect for one year.

Matthew S. Axelrod,

Assistant Secretary of Commerce, for Export Enforcement.

[FR Doc. 2024–07303 Filed 4–4–24; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–870]

Certain New Pneumatic Off-The-Road Tires From India: Preliminary Results of Countervailing Duty Administrative Review; 2022

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

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that countervailable subsidies were provided to producers and/or exporters of certain new pneumatic off-the-road tires (OTR tires) from India, during the period of review (POR) January 1, 2022, through December 31, 2022. Interested parties are invited to comment on these preliminary results.

DATES: Applicable April 5, 2024.

FOR FURTHER INFORMATION CONTACT: Austin Davison or Mark Hoadley, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2811 and (202) 482–3148, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 9, 2023, Commerce published the initiation of this administrative review of the countervailing duty order on OTR tires from India.[1] The mandatory company respondents are ATC Tires Private Limited (ATC) and Balkrishna Industries Ltd. On November 9, 2023, Commerce extended the time limit for these preliminary results to March 29, 2024.[2]

For a complete description of the events that followed the initiation of the review, *see* the Preliminary Decision Memorandum.[3] A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade/gov/public/FRNoticesListLayout.aspx.*

Scope of the Order

The merchandise covered by the order is OTR tires. OTR tires are tires with an off road tire size designation. The tires included in the scope may be either tube-type or tubeless, radial, or non-radial, regardless of whether for original equipment manufacturers or the replacement market. For a complete description of the scope of this order, *see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs preliminarily found to be countervailable, Commerce preliminarily determines that there is a subsidy, *i.e.,* a financial contribution from an authority that gives rise to a benefit to the recipient and that the

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 29885 (May 9, 2023).

[2] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Review,'' dated November 9, 2023.

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review of the Countervailing Duty Order on Off-the-Road Tires from India; 2022,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

subsidy is specific.[4] For a full description of the methodology underlying Commerce's preliminary conclusions, *see* the Preliminary Decision Memorandum.

Companies Not Selected for Individual Examination

The Act and Commerce's regulations do not directly address the subsidy rate to be applied to companies not selected for individual examination where Commerce limits its examination in an administrative review pursuant to section 777A(e)(2) of the Act. However, Commerce normally determines the rates for non-selected companies in reviews in a manner that is consistent with section 705(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation. Section 777A(e)(2) of the Act provides that ''the individual countervailable subsidy rates determined under subparagraph (A) shall be used to determine the all-others rate under section 705(c)(5) {of the Act}.'' Section 705(c)(5)(A) of the Act states that for companies not investigated, in general, we will determine an all-others rate by weight averaging the countervailable subsidy rates established for each of the companies individually investigated, excluding zero and *de minimis* rates or any rates based solely on the facts available.

Accordingly, to determine the rate for companies not selected for individual examination, Commerce's practice is to weight average the net subsidy rates for the selected mandatory respondents, excluding rates that are zero, *de minimis,* or based entirely on facts available.[5] We preliminarily determine that ATC received countervailable subsidies that are above *de minimis* and are not based entirely on facts available. Therefore, we preliminarily determine to apply the net subsidy rates calculated for ATC. The companies for which a review was requested, which were not selected as mandatory respondents or found to be cross-owned with a mandatory respondent, are listed in Appendix II.

Preliminary Results of Review

Commerce preliminarily determines the net countervailable subsidy rates exist for the period January 1, 2022, through December 31, 2022:

Company	Subsidy rate (percent *ad valorem*)
ATC Tires Private Limited[6]	1.83
Balkrishna Industries Ltd	*0.43
Companies Not Selected for Individual Review[7]	1.83

* *de minimis*.

Disclosure and Public Comment

Commerce intends to disclose its calculations and analysis performed to interested parties for these preliminary results within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance. Commerce will notify interested parties of the deadline for submission of case briefs. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[8] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[9]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[10] Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[11]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. Hearing requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. An electronically filed hearing request must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5 p.m. Eastern Time, within 30 days of the publication date of this notice. If a request for a hearing is made, parties will be notified of the time and date of the hearing.[12]

Final Results of Review

Unless the deadline is extended, Commerce intends to issue the final results of this administrative review, which will include the results of Commerce's analysis of the issues raised in the case briefs, within 120 days after the date of the preliminary results, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Assessment Rates

In accordance with 19 CFR 351.221(b)(4)(i), Commerce preliminarily assigned a subsidy rate in the amount for the producers/exporters shown above. Upon completion of the administrative review, consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**.

If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

In accordance with section 751(a)(2)(C) of the Act, Commerce also

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

[5] *See, e.g., Certain Pasta from Italy: Final Results of the 13th (2008) Countervailing Duty Administrative Review,* 75 FR 37386, 37387 (June 29, 2010).

[6] As discussed in the Preliminary Decision Memorandum, Commerce preliminarily finds ATC Tires AP Private Ltd to be cross-owned with ATC.

[7] *See* Appendix II for the list of these companies.

[8] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

[9] *See* 19 CFR 351.309(c)(2) and (d)(2).

[10] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[11] *See APO and Service Final Rule.*

[12] *See* 19 CFR 351.310(d).

intends upon publication of the final results, to instruct CBP to collect cash deposits of the estimated countervailing duties in the amounts calculated in the final results of this review for the respective companies listed above with regard to shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. If the rate calculated in the final results is zero or *de minimis,* no cash deposit will be required on shipments of the subject merchandise entered or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review.

For all non-reviewed firms, CBP will continue to collect cash deposits of estimated countervailing duties at the all-others rate or the most recent company-specific rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Interested Parties

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

Dated: March 29, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I—List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Rate for Non-Examined Companies
V. Subsidies Valuation
VI. Interest Rate Benchmarks, Discount Rates, and Benchmarks for Measuring the Adequacy of Remuneration
VII. Analysis of Programs
VIII. Recommendation

Appendix II—List of Companies Not Selected for Individual Review

1. Aakriti Manufacturing Pvt. Ltd.
2. Apollo Tyres Ltd.
3. Asian Tire Factory Limited.
4. Asiatic Tradelinks Private Limited.
5. Cavendish Industries Ltd.
6. Ceat Ltd.
7. Celite Tyre Corporation.
8. Emerald Resilient Tyre Manufacturer.
9. Forech India Private Limited.
10. HRI Tires India.
11. Innovative Tyres & Tubes Limited.
12. JK Tyre & Industries Ltd.
13. John Deere India Pvt. Ltd.
14. K.R.M. Tyres.
15. Mahansaria Tyres Private Limited.
16. MRF Limited.
17. MRL Tyres Limited (Malhotra Rubbers Ltd.).
18. Neosym Industry Limited.
19. OTR Laminated Tyres (I) Pvt. Ltd.
20. Royal Tyres Private Limited.
21. Rubberman Enterprises Pvt. Ltd.
22. Speedways Rubber Company.
23. Sun Tyre And Wheel Systems.
24. Sundaram Industries Private Limited.
25. Superking Manufacturers (Tyre) Pvt., Ltd.
26. TVS Srichakra Limited.
27. Ultra Mile.

[FR Doc. 2024–07281 Filed 4–4–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–842]

Certain Uncoated Paper From Brazil: Preliminary Results of Antidumping Duty Administrative Review; 2022–2023

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

SUMMARY: The U.S. Department of Commerce (Commerce) is conducting an administrative review of the antidumping duty (AD) order on certain uncoated paper (uncoated paper) from Brazil for the period of review (POR) March 1, 2022, through February 28, 2023. Commerce preliminarily finds that Suzano S.A. (Suzano) made sales of subject merchandise at prices below normal value (NV) during the POR, and finds that Sylvamo do Brasil Ltda. (SVBR) and Sylvamo Exports Ltda. (SVEX) (collectively, Sylvamo) did not make sales of subject merchandise at prices below NV during the POR. We invite interested parties to comment on these preliminary results.

DATES: Applicable April 5, 2024.

FOR FURTHER INFORMATION CONTACT: Christopher Maciuba or Nathan James, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0413 or (202) 482–5305, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 9, 2023, Commerce initiated an administrative review of the AD order on uncoated paper from Brazil,[1] in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).[2] This review covers two producers/exporters of subject merchandise, Suzano [3] and Sylvamo.[4]

On November 9, 2023, Commerce extended the deadline for these preliminary results until March 29, 2024.[5] For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[6]

Scope of the Order

The merchandise subject to the *Order* is uncoated paper from Brazil. For a full description of the scope, *see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Act. We calculated constructed export price in accordance with section 772 of the Act. We calculated NV in accordance with section 773 of the Act.

For a full description of the methodology underlying these preliminary results, *see* the Preliminary Decision Memorandum. A list of the topics discussed in the Preliminary Decision Memorandum is included as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Preliminary Results of the Review

We preliminarily determine that the following weighted-average dumping

[1] *See Certain Uncoated Paper from Australia, Brazil, Indonesia, the People's Republic of China, and Portugal: Amended Final Affirmative Antidumping Determinations for Brazil and Indonesia and Antidumping Duty Orders,* 81 FR 11174 (March 3, 2016) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 29881 (May 9, 2023).

[3] Commerce previously determined that Suzano is the successor-in-interest to Suzano Papel e Celulose S.A. *See Certain Uncoated Paper from Brazil: Final Results of Antidumping Duty Administrative Review; 2019–2020,* 86 FR 55820 (October 7, 2021).

[4] Commerce previously determined that SVBR is the successor-in-interest to International Paper do Brasil Ltda. and that SVEX is the successor-in-interest to International Paper Exportadora Ltda. *See Certain Uncoated Paper from Brazil: Final Results of Antidumping Duty Changed Circumstances Review,* 87 FR 1395 (January 11, 2022).

[5] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated November 9, 2023.

[6] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review of the Antidumping Duty Order on Certain Uncoated Paper from Brazil; 2022–2023,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

margins exist for the period March 1, 2022, through February 28, 2023:

Exporter/producer	Weighted-average dumping margin (percent)
Suzano S.A	3.49
Sylvamo do Brasil Ltda./Sylvamo Exports Ltda	0.00

Disclosure and Public Comment

We intend to disclose the calculations performed to parties within five days after public announcement of the preliminary results or, if there is no public announcement, within five days of the date of publication of this notice.[7] Interested parties may submit case briefs no later than 30 days after the date of publication of this notice.[8] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[9] Interested parties who submit case or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[10]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[11] 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 issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[12]

Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS.[13] Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants and whether any participant is a foreign national; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in case and rebuttal briefs.[14] If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. A hearing request must be filed electronically using ACCESS and received in its entirety by 5:00 p.m. Eastern Time within 30 days after the publication of this notice.

Assessment Rates

Upon completion of the final results of this administrative review, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.[15] Pursuant to 19 CFR 351.212(b)(1), if the weighted-average dumping margin for Suzano or Sylvamo is not zero or *de minimis* (*i.e.,* less than 0.50 percent) in the final results of this review, we will calculate importer-specific assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales. If either respondent's weighted-average dumping margin is zero or *de minimis* in the final results of review, or if an importer-specific assessment rate is zero or *de minimis,* Commerce will instruct CBP to liquidate appropriate entries without regard to antidumping duties. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review, and for future deposits of estimated duties, where applicable.[16]

In accordance with Commerce's ''automatic assessment'' practice, for entries of subject merchandise during the POR produced by Suzano or Sylvamo for which the company did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate those entries at the all-others rate established in the original less-than-fair-value (LTFV) investigation (*i.e.,* 27.11 percent) [17] if there is no rate for the intermediate company(ies) involved in the transaction.[18]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for the companies listed above will be equal to the weighted-average dumping margins established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for merchandise exported by a company not covered in this review, but covered in a prior segment of the proceeding, the cash deposit rate will be the company-specific rate published for the most recently-completed segment in which it was reviewed; (3) if the exporter is not a firm covered in this review or in the original LTFV investigation, but the producer is, then the cash deposit rate will be the rate established for the most recently-completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 27.11 percent, the all-others rate established in the LTFV investigation.[19] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Final Results of Review

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, including the results of its analysis of

[7] *See* 19 CFR 351.224(b).

[8] *See* 19 CFR 351.309(c)(1)(ii); *see also* 19 CFR 351.303 (for general filing requirements).

[9] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023).

[10] *See* 19 351.309(c)(2) and (d)(2).

[11] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[12] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule,* 88 FR 67069 (September 29, 2023).

[13] *See* 19 CFR 351.310(c).

[14] *See* 19 CFR 351.310.

[15] *See* 19 CFR 351.212(b).

[16] *See* section 751(a)(2)(C) of the Act.

[17] *See Order,* 81 FR at 11176.

[18] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[19] *See Order,* 81 FR at 11176.

the issues raised in any written briefs, no later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

Commerce is issuing and publishing these results in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.213(h)(2) and 19 CFR 351.221(b)(4).

Dated: March 29, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2024–07234 Filed 4–4–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–869]

Certain New Pneumatic Off-the-Road Tires From India: Preliminary Results and Partial Recission of Antidumping Duty Administrative Review; 2022–2023

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

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that certain producers/exporters subject to this administrative review made sales of subject merchandise at less than normal value (NV) during the period of review (POR) March 1, 2022, through February 28, 2023. We are also rescinding this administrative review, in part, with respect to 10 companies because these companies had no reviewable entries of subject merchandise during the POR. We invite interested parties to comment on these preliminary results.

DATES: Applicable April 5, 2024.

FOR FURTHER INFORMATION CONTACT: Lilit Astvatsatrian, AD/CVD Operations, Office IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6412.

SUPPLEMENTARY INFORMATION:

Background

On March 6, 2017, Commerce published in the **Federal Register** an antidumping duty order on off-the-road tires from India.[1] On May 9, 2023, based on timely requests for review, we initiated an administrative review of the *Order* covering 24 companies.[2] On November 4, 2023, we extended the time limit for these preliminary results to March 29, 2024.[3] For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[4]

Scope of the Order

The merchandise subject to the *Order* is certain new pneumatic off-the-road tires from India. For a full description of the scope of the *Order,* see the Preliminary Decision Memorandum.

Partial Recission of Administrative Review

Pursuant to 19 CFR 351.213(d)(3), it is Commerce's practice to rescind an administrative review of an antidumping duty order where it concludes that there were no suspended entries of subject merchandise during the POR.[5] Normally, upon completion of an administrative review, the suspended entries are liquidated at the antidumping duty assessment rate for the review period.[6] Therefore, for an administrative review to be conducted, there must be a reviewable, suspended entry that Commerce can instruct U.S. Customs and Border Protection (CBP) to liquidate at the calculated antidumping duty assessment rate for the review period.[7] On December 22, 2023, we notified parties of our intent to rescind the instant review regarding the companies listed in Appendix III because there were no reviewable, suspended entries of subject merchandise from these companies during the POR and invited interested parties to comment.[8] No parties commented on our intent to rescind the review, in part. In the absence of any suspended entries of subject merchandise from these companies during the POR, we are rescinding this administrative review for the companies listed in Appendix III, in accordance with 19 CFR 351.213(d)(3).

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). We calculated export price and constructed export price in accordance with section 772 of the Act. We calculated NV in accordance with section 773 of the Act.

For a full description of the methodology underlying these preliminary results, *see* the Preliminary Decision Memorandum. A list of the topics discussed in the Preliminary Decision Memorandum is attached as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a

[1] *See Certain New Pneumatic Off-the-Road Tires from India: Antidumping Duly Order,* 82 FR 12553 (March 6, 2017) (*Order*); *see also Certain New Pneumatic Off-the-Road Tires from India: Notice of Correction to Antidumping Duty Order,* 82 FR 25598 (June 2, 2017) (*Order Correction*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 29881 (May 9, 2023).

[3] *See* Memorandum, ''Extension of Deadline for Preliminary Results,'' dated November 8, 2023.

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review of the Antidumping Duty Order on Certain New Pneumatic Off-the-Road Tires from India; 2022–2023,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[5] *See, e.g., Certain Carbon and Alloy Steel Cut-to Length Plate from the Federal Republic of Germany: Recission of Antidumping Administrative Review; 2020–2021,* 88 FR 4154 (January 24, 2023).

[6] *See* 19 CFR 351.212(b)(1).

[7] *See, e.g., Shanghai Sunbeauty Trading Co.* v. *United States,* 380 F. Supp. 3d 1328, 1337 (CIT 2019), at 12 (referring to section 751(a) of the Act, the CIT held: ''While the statute does not explicitly require that an entry be suspended as a prerequisite for establishing entitlement to a review, it does explicitly state the determined rate will be used as the liquidation rate for the reviewed entries. This result can only obtain if the liquidation of entries has been suspended''; *see also Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2018–2019,* 86 FR 36102, and accompanying Issues and Decision Memorandum at Comment 4; and *Solid Fertilizer Grade Ammonium Nitrate from the Russian Federation: Notice of Rescission of Antidumping Duty Administrative Review,* 77 FR 65532 (October 29, 2012) (noting that ''for an administrative review to be conducted, there must be a reviewable, suspended entry to be liquidated at the newly calculated assessment rate'').

[8] *See* Memorandum, ''Notice of Intent to Rescind Review, In Part,'' dated December 22, 2023.

complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Rate for Non-Examined Companies

The statute and Commerce's regulations do not address the rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a market economy investigation, for guidance when calculating the rate for companies which were not selected for individual examination in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely on the basis of facts available.

We preliminarily calculated dumping margins for the two mandatory respondents, ATC Tires Private Limited and ATC Tires AP Private Ltd. (collectively, ATC) and Asian Tire Factory Ltd. and Lyallpur Rubber Mills (collectively, ATF), of 2.68 percent and 3.18 percent, respectively, and we have assigned to the non-selected companies a rate of 2.71 percent, which is the weighted average of ATC's and ATF's dumping margins, weighted by their publicly ranged U.S. sales values.[9]

Preliminary Results of the Review

As a result of this review, we preliminarily determine the following estimated weighted-average dumping margins exist for the period March 1, 2022, through February 28, 2023:

Producer or exporter	Weighted-average dumping margin (percent)
ATC Tires Private Limited; ATC Tires AP Private Limited	2.68
Asian Tire Factory Ltd.; Lyallpur Rubber Mills	3.18
Companies Not Selected for Individual Review[10]	2.71

Disclosure and Public Comment

We intend to disclose the calculations performed in connection with these preliminary results to interested parties within five days after the date of publication of this notice in the **Federal Register**.[11] Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[12] Interested parties who submit case briefs or rebuttal briefs in this administrative review must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[13]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings, we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide, at the beginning of their briefs, a public executive summary for each issue raised in their briefs.[14] 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 issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. Oral presentations at the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing.[15]

All submissions, including case and rebuttal briefs, as well as hearing requests, should be filed via ACCESS.[16] An electronically filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the established deadline. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[17]

Final Results of Review

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, no later than 120 days after the date of publication of this notice in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Assessment Rates

Upon completion of this administrative review, pursuant to section 751(a)(2)(A) of the Act, Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.

Pursuant to 19 CFR 351.212(b)(1), because ATC reported the entered value of its U.S. sales, we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the examined sales to the total entered value of the sales for which entered value was reported. ATF did not report the actual entered value for its U.S. sales; thus, we calculated importer-specific per-unit duty assessment rates by aggregating the total amount of antidumping duties calculated for the

[9] With two respondents under examination, Commerce normally calculates: (A) a weighted-average of the dumping margins calculated for the examined respondents; (B) a simple average of the dumping margins calculated for the examined respondents; and (C) a weighted-average of the dumping margins calculated for the examined respondents using each company's publicly ranged U.S. sale quantities for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. *See, e.g., Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010). *See also* Memorandum, ''Calculation of the Review-Specific Average Rate,'' dated concurrently with, and hereby adopted by, this notice.

[10] The exporters or producers not selected for individual review are listed in Appendix II.

[11] *See* 19 CFR 351.224(b).

[12] *See* 19 CFR 351.309(d)(1); see also *Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

[13] *See* 19 CFR 351.309(c)(2) and (d)(2).

[14] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[15] *See* 19 CFR 351.310(d).

[16] *See* 19 CFR 351.303.

[17] *See APO and Service Final Rule.*

examined sales and dividing this amount by the total quantity of those sales. Where either the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

For entries of subject merchandise during the POR produced by either of the individually examined respondents for which they did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate these entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[18]

For the companies listed in Appendix II which were not selected for individual review, we will assign an assessment rate based on the review-specific rate, calculated as noted in the ''Rate for Non-Examined Companies'' section, above.

For the companies listed in Appendix III for which we are rescinding this review, we will instruct CBP to assess antidumping duties on all appropriate entries at a rate equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, in accordance with 19 CFR 351.212(c)(l)(i). Commerce intends to issue these rescission instructions to CBP no earlier than 35 days after the date of publication of this notice in the **Federal Register**.

Commerce intends to issue assessment instructions to CBP regarding ATC, ATF, and the companies listed in Appendix II no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review and for future deposits of estimated duties, where applicable.[19]

[18] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[19] *See* section 751(a)(2)(C) of the Act.

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for the companies listed above will be that established in the final results of this review, except if the rate is less than 0.05 percent and therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously investigated or reviewed companies not covered by this review, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair-value (LTFV) investigation, but the producer is, then the cash deposit rate will be the rate established for the most recently-completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 3.67 percent, the all-others rate established in the LTFV investigation.[20] These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing and the subsequent assessment of doubled antidumping duties, and/or an increase in the amount of antidumping by the amount of countervailing duties.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

[20] *See Order,* 82 FR at 12553, 12554.

Dated: March 29, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I—List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Discussion of the Methodology
V. Recommendation

Appendix II—Companies Not Selected for Individual Review

1. Apollo Tyres Ltd.
2. Balkrishna Industries Ltd.[21]
3. CEAT Ltd.
4. Emerald Resilient Tyre Manufacturer
5. HRI Tires India
6. JK Tyres and Industries Ltd.
7. K.R.M. Tyres
8. Mahansaria Tyres Private Limited
9. MRF Limited
10. MRL Tyres Limited (Malhotra Rubbers Ltd.)
11. Speedways Rubber Company
12. TVS Srichakra Limited

Appendix III—Companies With No Reviewable Entries

1. Aakriti Manufacturing Pvt. Ltd.
2. Cavendish Industries Ltd.
3. Celite Tyre Corporation
4. John Deere India Pvt. Ltd.
5. OTR Laminated Tyres (I) Pvt. Ltd.
6. Royal Tyres Private Limited
7. Sun Tyre And Wheel Systems
8. Sundaram Industries Private Limited
9. Tyre Experts LLP
10. Ultra Mile

[FR Doc. 2024–07282 Filed 4–4–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–471–807]

Certain Uncoated Paper From Portugal: Preliminary Results of the Administrative Review of the Antidumping Duty Order; 2022–2023

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

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that the sole producer or exporter subject to this administrative review made sales of certain uncoated paper (uncoated paper) from Portugal at below normal value during the period of

[21] Subject merchandise produced and exported by Balkrishna Industries Ltd. (BKT) was excluded from the *Order. See Order Correction,* 82 FR at 25598. Accordingly, BKT is only covered by this administrative review for subject merchandise produced in India where BKT acted as either the manufacturer or exporter (but not both).

review (POR) March 1, 2022, through February 28, 2023. We invite interested parties to comment on these preliminary results.

DATES: Applicable April 5, 2024.

FOR FURTHER INFORMATION CONTACT: Eric Hawkins, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1988.

SUPPLEMENTARY INFORMATION:

Background

On May 9, 2023, Commerce initiated an administrative review of the antidumping duty order on uncoated paper from Portugal,[1] in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).[2] This review covers one producer/exporter of subject merchandise, The Navigator Company, S.A. (Navigator).

On November 3, 2023, Commerce extended the time limit for completing the preliminary results of this review until March 29, 2024.[3] For details regarding the events that occurred subsequent to the initiation of the review, *see* the Preliminary Decision Memorandum.[4]

Scope of the Order

The products covered by the *Order* are certain uncoated paper products from Portugal. For a complete description of the scope, *see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Act. We calculated constructed export price in accordance with section 772 of the Act. We calculated normal value in accordance with section 773 of the Act. For a full description of the methodology underlying these preliminary results, *see* the Preliminary Decision Memorandum. A list of topics included in the Preliminary Decision Memorandum is included as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum is available at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Preliminary Results of Review

We preliminarily determine that the following estimated weighted-average dumping margin exists for the period March 1, 2022, through February 28, 2023:

Exporter/producer	Weighted-average dumping margin (percent)
The Navigator Company, S.A	1.07

Disclosure and Public Comment

We intend to disclose the calculations performed to parties within five days after public announcement of the preliminary results or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register** in accordance with 19 CFR 351.224(b).

Pursuant to 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[5] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[6] As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their briefs that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[7] 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 issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[8]

Interested parties who wish to request a hearing must do so within 30 days of publication of these preliminary results by submitting a written request to the Assistant Secretary, filed electronically via ACCESS.[9] Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs.[10] If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm the date and time of the hearing two days before the scheduled date. Parties are reminded that all briefs and hearing requests must be filed electronically using ACCESS and received successfully in their entirety by 5 p.m. Eastern Time on the due date.

Assessment Rates

Upon completion of the final results of this administrative review, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review. If Navigator's weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent) in the final results of this review, we will calculate importer-specific *ad valorem* antidumping duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1). We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate calculated in the final results of this review is not zero or *de minimis.* If Navigator's

[1] *See Certain Uncoated Paper from Australia, Brazil, Indonesia, the People's Republic of China, and Portugal: Amended Final Affirmative Antidumping Determinations for Brazil and Indonesia and Antidumping Duty Orders,* 81 FR 11174 (March 3, 2016) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 29881 (May 9, 2023).

[3] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated November 3, 2023.

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review of the Antidumping Duty Order on Certain Uncoated Paper from Portugal; 2022–2023,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[5] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Procedures*).

[6] *See* 19 CFR 351.309(c)(2) and (d)(2).

[7] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[8] *See APO and Service Procedures.*

[9] *See* 19 CFR 351.310(c).

[10] *See* 19 CFR 351.310.

weighted-average dumping margin is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.[11]

In accordance with Commerce's ''automatic assessment'' practice, for entries of subject merchandise during the POR produced by Navigator for which it did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate those entries at the all-others rate established in the original less-than-fair value (LTFV) investigation (*i.e.,* 7.80 percent) [12] if there is no rate for the intermediate company(ies) involved in the transaction.[13]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for Navigator in the final results of review will be equal to the weighted-average dumping margin established in the final results of this administrative review except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for merchandise exported by producers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment of this proceeding in which they were reviewed; (3) if the exporter is not a firm covered in this review or the original LTFV investigation but the producer is, then the cash deposit rate will be the rate established for the most recently-completed segment of this proceeding for the producer of the merchandise; (4) the cash deposit rate for all other producers or exporters will continue to be 7.80 percent,[14] the all-others rate established in the LTFV investigation. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Final Results of Review

Unless extended, Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification to Interested Parties

This administrative review and notice are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213 and 351.221(b)(4).

Dated: March 29, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary, for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2024–07233 Filed 4–4–24; 8:45 am]

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[11] *See* section 751(a)(2)(C) of the Act.

[12] *See Order.*

[13] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[14] *See Order.*

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD752]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Exempted Fishing Permits

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

ACTION: Notice of receipt of two applications for exempted fishing permits; request for comments.

SUMMARY: NMFS announces the receipt of two applications for exempted fishing permits (EFPs) from the Florida Fish and Wildlife Conservation Commission (FWC). If granted, the EFPs would authorize limited recreational harvest of red snapper outside of any Federal recreational season in South Atlantic Federal waters and exempt that harvest from the red snapper recreational bag and possession limits, recreational annual catch limits (ACLs), and accountability measures (AMs). FWC's projects are intended to test alternative recreational management strategies that could be used by the South Atlantic Fishery Management Council (Council) to reduce the numbers of discards of red snapper and other federally managed snapper-grouper species, create additional opportunities to participate in sustainable recreational harvest, and improve angler satisfaction.

DATES: Written comments must be received on or before April 22, 2024.

ADDRESSES: You may submit comments on the applications, identified by [NOAA–NMFS–2024–0035] by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Visit *https://www.regulations.gov* and type [NOAA–NMFS–2024–0035] in the Search box. Click the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Rick DeVictor, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *https://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 EFP applications may be obtained from the Southeast Regional Office website at *https://www.fisheries.noaa.gov/southeast/recreational-fishing/south-atlantic-red-snapper-exempted-fishing-permit-applications.* This notice discusses applications 1 and 3 on the website.

FOR FURTHER INFORMATION CONTACT: Caroline Potter, 727–824–5305; email: *caroline.potter@noaa.gov.*

SUPPLEMENTARY INFORMATION: The EFPs are requested under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*), and regulations at 50 CFR 600.745(b) concerning exempted fishing.

The projects described in these EFP requests are two of several projects that NMFS has recommended for funding based on a notice of funding opportunity that NMFS published last fall, seeking projects that would explore new approaches to better understand and reduce red snapper dead discards and increase fishing opportunities in the South Atlantic snapper-grouper fishery.

The most recent South Atlantic red snapper stock assessment (Southeast Data, Assessment, and Review (SEDAR) 73, 2021) indicates that the South Atlantic red snapper stock is undergoing overfishing and is overfished. Discard mortality continues to be the primary source of fishing mortality, with a high number of discards coming from the recreational sector. Therefore, NMFS has identified a need to test management strategies that could be used by the Council to reduce recreational discards of red snapper and other managed snapper-grouper species, ensure opportunities for sustainable harvest, and improve angler satisfaction.

Considering this need, the FWC has proposed two projects that would accomplish the following objectives: (1) Directly collaborate with members of the snapper-grouper recreational sector and collect catch and discard information at a representative scale within the snapper-grouper fishery; (2) Recruit recreational fishermen to test a unique snapper-grouper aggregate recreational bag limit, and compare that with control groups to quantify the potential impact alternative management strategies have on reducing the magnitude of snapper-grouper regulatory discards; (3) Allow a select number of recreational fishermen recruited for these projects to harvest red snapper outside of the South Atlantic Federal red snapper recreational season, accompanied by a mandatory reporting requirement and provisions for validation and proof of participation; (4) Develop a unique web-based application to record information from project participants; (5) Develop an education course required for all project participants that highlights best fishing practices, species identification, and methods to safely descend fish experiencing barotrauma; and (6) Evaluate recreational fisherman satisfaction through pre- and post-participation surveys and semi-structured interviews with project participants.

NMFS notes that this notification of receipt of applications for EFPs encompasses two FWC projects. Each of these projects is identical in project scope, purpose, and exempted Federal regulations. The primary differences between the two requested projects are location of the project and the maximum allowed number of recreational fishing trips per participant for each location.

One proposed project boundary is offshore of the east coast of Florida from the Florida/Georgia state line south to 28°35.1′ north latitude in the Atlantic Ocean (due east of the NASA Vehicle Assembly Building, Cape Canaveral, Florida). The other project boundary is offshore of the east coast of Florida from 28°35.1′ north latitude in the Atlantic Ocean (due east of the NASA Vehicle Assembly Building, Cape Canaveral, Florida) south to the Dry Tortugas, the southern boundary of the South Atlantic Fishery Management Council jurisdictional waters(50 CFR 600.105(c)). The project locations includes state and Federal waters, but FWC expects that the majority of snapper-grouper harvest and fishing effort would occur in Federal waters.

The EFPs would begin on July 1, 2024, and end on June 30, 2025. FWC would solicit applications from individual recreational fishermen who would be entered into a lottery to participate in either study. The application and lottery process, both administered by FWC, would occur once every 3 months and FWC would select 200 participants for each 3-month study. Participants would be screened by the FWC for resource violations and randomly assigned to either a control group or an experimental group. Participants in the northern study would be referred to as the ''Experimental Hot Spot Fleet'' and participants in the southern study would be referred to as the ''Southeast Florida Snapper Grouper Fleet.'' Each participant would be required to hold a valid saltwater recreational fishing license issued by the State of Florida (or be state exempt), have declared themselves a Florida State Reef Fish Survey angler, and take an educational course aimed at reducing discard mortality of snapper-grouper species. The EFPs would only apply to recreational fishermen who apply for and are selected to be part of FWC's Experimental Hot Spot Fleet or Southeast Florida Snapper-Grouper Fleet. Therefore, under each EFP, for each 3-month period, FWC would be able to account for and provide NMFS with a list of participants (*e.g.,* state license, registration of each vessel and vessel name during designated fishing trips, name of participants and contact information, *etc.*) to be covered under each EFP before operations begin under the EFPs.

Every 3 months during the 12-month fishing period of each EFP, half of the fishermen would be selected for a control group and the other half for an experimental group. Participants assigned to the control group of either fleet would follow the current recreational Federal regulations for snapper-grouper species. Each participant in the Experimental Hot Spot Fishing Fleet, regardless of group assignment, would be able to take a maximum of three recreational fishing trips per 3-month period. Each participant in the Southeast Florida Snapper-Grouper Fleet, regardless of group assignment, would be able to take a maximum of two recreational fishing trips per 3-month period.

For both fleets, participants assigned to an experimental group would be permitted to harvest no more than 15 fish under a unique snapper-grouper aggregate bag limit per person per day in state and Federal waters combined, in addition to the three red snapper described below. Participants in an experimental group would be required to stop directed snapper-grouper recreational trips once their unique aggregate snapper-grouper bag limit has been reached, and they would not be allowed to target or harvest any snapper-grouper species managed by the Council for the remainder of the trip. Participants may then target other species such as coastal migratory pelagics and dolphinfish. In addition to the unique aggregate bag limit described above, participants in an experimental group would be allowed to harvest three red snapper outside of any Federal red

snapper recreational fishing season under the EFPs until the unique aggregate snapper-grouper bag limit is reached. If approved, the EFPs would exempt those recreational fishermen in an experimental group participating in FWC's Experimental Hot Spot Fleet or Southeast Florida Snapper-Grouper Fleet from the Federal regulations at 50 CFR 622.183(b)(5) (recreational sector closures for red snapper), 50 CFR 622.187(b)(9) (bag and possession limits for red snapper), and 50 CFR 622.193(y)(2) (ACLs and AMs for red snapper). The FWC is not requesting exemptions from any Federal regulations other than these. Participants would have to abide by all fishery regulations otherwise not exempted from this study.

Under the EFPs, the unique 15-fish snapper-grouper aggregate recreational bag limit requested by FWC is as follows:

- Only 1 fish can be gag, black grouper, or scamp.
- Up to 2 fish can be red grouper, yellowfin grouper, yellowmouth grouper, coney, graysby, red hind, or rock hind.
- Only 1 fish can be red porgy, blueline tilefish, or golden tilefish.
- Only 1 fish can be greater amberjack.
- Up to 3 fish can be lesser amberjack, almaco jack, or banded rudderfish.
- Up to 5 fish can be black sea bass.
- Up to 5 fish can be gray triggerfish.
- Up to 10 fish can be grunts.
- Up to 10 fish can be Atlantic spadefish or bar jack.
- Up to 10 fish can be porgies (excluding red porgy).
- Up to 10 fish can be schoolmaster snapper, gray snapper, lane snapper, yellowtail snapper, queen snapper, silk snapper, or blackfin snapper.
- Up to 5 fish can be vermilion snapper, cubera snapper, or mutton snapper.

Until the unique snapper-grouper aggregate bag limit is reached, all species within the snapper-grouper fishery, except those with regulatory closures, could be harvested by participants. Should a regulatory closure occur for any species (other than red snapper), participants would be prohibited from harvesting those species. The requested recreational bag limits within FWC's proposed 15-fish snapper-grouper aggregate bag limit do not exceed current Federal recreational bag limits for any of the included snapper-grouper species. This aggregate bag limit is intended to cause recreational fishermen to reach their daily bag limit faster, which would then result in them stopping fishing. This would likely then lead to reduced discards and enhanced fisherman satisfaction across the snapper-grouper recreational sector. Throughout the duration of the proposed projects, the total amount of South Atlantic red snapper allowed to be harvested under these EFPs by the recreational fishermen is 3,600 on Experimental Hot Spot Fleet trips and 2,400 on Southeast Florida Snapper-Grouper Fleet trips.

Recreational fishermen can choose the date and time of each trip within each 3-month period of the project. Prior to taking a fishing trip, the selected participant, using their unique FWC provided identification number, must notify FWC 24 hours in advance of a planned trip and report the date and state registration number of the vessel they intend to fish from in order to receive an FWC authorization document, which must then be available to present to law enforcement if requested, either at sea or dockside. Selected participants can also elect to take their fishing trips on a charter vessel or headboat (for-hire). Aboard that for-hire vessel, only participants who have been selected to participate in an EFP and declared they are taking a trip authorized under an EFP on the identified for-hire vessel can take red snapper (if in an experimental group). As the vessel, private or for-hire, with the participant onboard is returning to port, the participant must hail in and let FWC know the estimated time and location of arrival. Upon return to port from a trip, all participants would be required to submit catch and discard data to the FWC within 48 hours through an FWC web-based application. To evaluate recreational fishermen satisfaction, FWC social scientists would conduct pre- and post-participation surveys and randomly select a subset of participants in each group to participate in semi-structured interviews.

NMFS finds the applications warrants further consideration based on a preliminary review. Possible conditions the agency may impose on the EFPs, if granted, include but are not limited to, a prohibition on fishing within marine protected areas, marine sanctuaries, or special management zones without additional authorization.

A final decision on issuance of the EFPs will depend on NMFS' review of public comments received on the applications, consultations with the appropriate fishery management agencies of the affected states, the Council, and the U.S. Coast Guard, and a determination that the activities to be taken under the EFPs are consistent with all other applicable laws.

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

Dated: April 1, 2024.

Everett Wayne Baxter,

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

[FR Doc. 2024–07270 Filed 4–4–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD756]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Exempted Fishing Permit

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

ACTION: Notice of receipt of an application for exempted fishing permit; request for comments.

SUMMARY: NMFS announces the receipt of an application for an exempted fishing permit (EFP) from the Florida Fish and Wildlife Conservation Commission (FWC). If granted, the EFP would authorize limited recreational harvest of red snapper outside of any Federal recreational season in South Atlantic Federal waters and exempt that harvest from the red snapper recreational bag and possession limits, recreational annual catch limits (ACLs), and accountability measures (AMs). FWC's project is intended to test alternative recreational management strategies that could be used by the South Atlantic Fishery Management Council (Council) to reduce the numbers of discards of red snapper and other federally managed snapper-grouper species, create additional opportunities to participate in sustainable recreational harvest, and improve angler satisfaction.

DATES: Written comments must be received on or before April 22, 2024.

ADDRESSES: You may submit comments on the application, identified by [NOAA–NMFS–2024–0036] by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Visit *https://www.regulations.gov* and type [NOAA–NMFS–2024–0036] in the Search box. Click the ''Comment'' icon, complete the required fields, and enter or attach your comments.

• *Mail:* Rick DeVictor, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *https://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 EFP application may be obtained from the Southeast Regional Office website at *https://www.fisheries.noaa.gov/southeast/recreational-fishing/south-atlantic-red-snapper-exempted-fishing-permit-applications.* This notice discuses application 2 on the website.

FOR FURTHER INFORMATION CONTACT: Caroline Potter, 727–824–5305; email: *caroline.potter@noaa.gov.*

SUPPLEMENTARY INFORMATION: The EFP is requested under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*), and regulations at 50 CFR 600.745(b) concerning exempted fishing.

The project described in this EFP request is one of several projects that NMFS has recommended for funding based on a notice of funding opportunity that NMFS published last fall, seeking projects that would explore new approaches to better understand and reduce red snapper dead discards and increase fishing opportunities in the South Atlantic snapper-grouper fishery.

The most recent South Atlantic red snapper stock assessment (Southeast Data, Assessment, and Review (SEDAR) 73, 2021) indicates that the South Atlantic red snapper stock is undergoing overfishing and is overfished. Discard mortality continues to be the primary source of fishing mortality, with a high number of discards coming from the recreational sector. Therefore, NMFS has identified a need for improved data to support the evaluation of alternative management strategies that could be used by the Council to reduce recreational discards of red snapper and other managed snapper-grouper species, ensure opportunities for sustainable harvest, and improve angler satisfaction.

Considering this need, FWC has proposed this project to accomplish the following objectives: (1) Collaborate with recreational vessel captains and recreational fishermen to collect catch and discard information within the snapper-grouper fishery; (2) Recruit charter vessel and private recreational vessel captains to test a unique snapper-grouper aggregate recreational bag limit and its impact on reducing the magnitude of regulatory discards; (3) Allow project participants to harvest red snapper outside of the Federal red snapper recreational season, accompanied by a mandatory reporting requirement and provisions for validation; (4) Develop a unique web-based application to record information from project participants; (5) Develop an education course required for all project participants; and (6) Evaluate recreational fishermen satisfaction through pre- and post-participation surveys.

The EFP would begin on July 1, 2024, and end on June 30, 2025. The project location would occur offshore of the east coast of Florida and include state and Federal waters from the Florida/Georgia state line south to a line running east from the NASA General Assembly Building in Cape Canaveral, Florida. For this project, FWC proposes to create a ''Study Fleet'' of five private recreational vessels and five charter vessels that would each take up to three fishing trips per quarter (a 3-month project period). The sampling period for the entire study would be 12 months and thus each quarter would last 3 months. All Study Fleet fishing trips would be limited to a maximum of six recreational fishermen per vessel (excluding the captain and crew of charter vessels) and all recreational fishermen onboard a selected vessel would be participants in the study. All recreational fishermen on project vessels would be required to fish with a single hook rig with a circle hook. The FWC Study Fleet would be allowed to retain up to a maximum vessel limit of 60 South Atlantic red snapper per day, regardless of the number of persons onboard the vessel. In addition, recreational fishermen onboard a vessel would be allowed to harvest no more than 15 fish under a unique snapper-grouper aggregate bag limit per person per day in state and Federal waters. All recreational fishermen onboard the selected vessels would be required to keep all snapper-grouper species that meet legal requirements, such as size limits, and would retain all red snapper caught, up to the 60 red snapper vessel limit, while trying to obtain the unique 15-fish snapper-grouper aggregate bag limit. Each recreational fisherman on a Study Fleet vessel trip would be required to stop directed snapper-grouper fishing once the unique snapper-grouper aggregate bag limit of 15-fish has been met or the vessel limit of 60 red snapper has been met, whichever occurs first. After meeting one of these limits, participants may target other species such as coastal migratory pelagics and dolphinfish, but they would be required to stop directed snapper-grouper fishing for the remainder of the trip.

If approved, the EFP would exempt recreational fishermen participating in FWC's Study Fleet from the Federal regulations at 50 CFR 622.183(b)(5) (recreational sector closures for red snapper), 50 CFR 622.187(b)(9) (bag and possession limits for red snapper), and 50 CFR 622.193(y)(2) (ACLs and AMs for red snapper). The FWC is not requesting exemptions from any Federal regulations other than these. Participants would have to abide by all fishery regulations otherwise not exempted from this study.

Under the EFP, the unique 15-fish snapper-grouper aggregate recreational bag limit requested by FWC is as follows:

- Only 1 fish can be gag, black grouper, or scamp.
- Up to 2 fish can be red grouper, yellowfin grouper, yellowmouth grouper, coney, graysby, red hind, or rock hind.
- Only 1 fish can be red porgy, blueline tilefish, or golden tilefish.
- Only 1 fish can be greater amberjack.
- Up to 3 fish can be lesser amberjack, almaco jack, or banded rudderfish.
- Up to 5 fish can be black sea bass.
- Up to 5 fish can be gray triggerfish.
- Up to 10 fish can be grunts.
- Up to 10 fish can be Atlantic spadefish or bar jack.
- Up to 10 fish can be porgies (excluding red porgy).
- Up to 10 fish can be schoolmaster snapper, gray snapper, lane snapper, yellowtail snapper, queen snapper, silk snapper, or blackfin snapper.
- Up to 5 fish can be vermilion snapper, cubera snapper, or mutton snapper.

Until the unique snapper-grouper aggregate bag limit is reached or the red snapper vessel limit is reached, all species within the snapper-grouper fishery, except those with regulatory closures, could be recreationally harvested by participants. However, species not listed above would not count towards the FWC's proposed 15-

fish snapper-grouper aggregate recreational bag limit. Should a regulatory closure occur for any species (other than red snapper), participants would be prohibited to harvest those species. This unique aggregate bag limit is intended to cause recreational fishermen to reach their daily bag limit faster which would then result in them stopping fishing for snapper-grouper species. This would then lead to reduced discards and enhanced fisherman satisfaction across the snapper-grouper recreational sector. Throughout the duration of the proposed project, recreational fishermen would harvest a maximum of 7,200 South Atlantic red snapper on Study Fleet trips.

If the project is approved, FWC would solicit applications from captains of charter vessels and private recreational vessels that fish within the proposed study location. Charter vessel captains are defined as someone who will be responsible for safe operation of the vessel during FWC Study Fleet trips and is licensed by the United States Coast Guard to carry passengers for hire and has one or more passengers onboard who are paying a fee to take or pursue an organism. Project charter vessels would need to have a valid Federal Charter Vessel/Headboat Permit for South Atlantic Snapper-Grouper. For this project, private recreational captains are defined as someone who will be responsible for the safe operation of the vessel during FWC Study Fleet trips and, if born after January 1, 1988, has successfully completed an approved boating safety course and obtained a Boating Safety Education Identification Card issued by FWC. A captain may be exempt from these requirements if they are licensed by the United States Coast Guard as master of a vessel or are a nonresident that has completed a National Association of State Boating Law Administrators approved boater safety course or equivalent examination from another state. Any private recreational captain or charter vessel captain that does not have a resource violation as determined by FWC would be eligible to participate in the FWC Study Fleet.

From the applications received from the public by FWC, FWC would select five private vessels and five charter vessels to be part of the FWC Study Fleet each quarter. Vessels would partly be selected based on the area intended to be fished, vessel type, and the homeport of these vessels. The selection criteria are intended to result in a comprehensive coverage of the study location. Both charter and private vessels would be limited to a maximum of six recreational fishermen (excluding the captain and crew of charter vessels) per designated fishing trip. The terms of the EFP would apply to all captains and recreational fishermen on the selected vessels during FWC Study Fleet trips. All charter vessels would be required to have the Federal Charter Vessel/Headboat Permit for South Atlantic Snapper-Grouper species and a Florida Saltwater Charter License prior to participating in the FWC Study Fleet. All recreational fishermen fishing from private vessels would be required to have a valid Florida recreational fishing license (or be exempt) and be signed up for Florida's State Reef Fish Survey prior to fishing aboard a trip as part of the FWC Study Fleet. All project participants fishing in the FWC Study Fleet would be required to view and complete an online educational course provided by the FWC. The EFP would only apply to the captains and vessels that are selected to be a part of the FWC Study Fleet. Therefore, FWC would be able to account for and provide NMFS with a list of participants (*e.g.,* state license, registration of each vessel and vessel name during designated fishing trips, name of participants and contact information, *etc.*) to be covered under the EFP before operations begin under the EFP.

Prior to taking a FWC Study Fleet fishing trip, each captain would have to coordinate the date/dates of the trip with FWC. Using their unique FWC provided identification number, captains would be required to notify FWC 24 hours prior to a planned project trip and report the date and state registration number of the vessel they intend to fish from in order to receive an FWC authorization document, which must be available to present to law enforcement if requested at-sea or dockside. When the FWC Study Fleet vessel returns to port, the captain must hail in and let FWC know the estimated time and location of arrival. Upon return to port from a trip, the captain and all recreational fishermen aboard a project vessel would be required to allow FWC to collect biological samples from harvested fish and conduct interviews. All captains would be required to report data through an FWC web-based application about their fishing trip within 48 hours of returning to port.

NMFS finds the application warrants further consideration based on a preliminary review. Possible conditions the agency may impose on the EFP, if granted, include but are not limited to, a prohibition on fishing within marine protected areas, marine sanctuaries, or special management zones without additional authorization.

A final decision on issuance of the EFP will depend on NMFS' review of public comments received on the application, consultations with the appropriate fishery management agencies of the affected states, the Council, and the U.S. Coast Guard, and a determination that the activities to be taken under the EFP are consistent with all other applicable laws.

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

Dated: April 1, 2024.

Everett Wayne Baxter,

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

[FR Doc. 2024–07272 Filed 4–4–24; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD714]

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Geophysical Surveys Related to Oil and Gas Activities in the Gulf of Mexico

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

ACTION: Notice of issuance of Letter of Authorization.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA), as amended, its implementing regulations, and NMFS' MMPA Regulations for Taking Marine Mammals Incidental to Geophysical Surveys Related to Oil and Gas Activities in the Gulf of Mexico, notification is hereby given that a Letter of Authorization (LOA) has been issued to WesternGeco for the take of marine mammals incidental to geophysical survey activity in the Gulf of Mexico (GOM).

DATES: The LOA is effective from May 1, 2024 through April 30, 2025.

ADDRESSES: The LOA, LOA request, and supporting documentation are available online at: *https://www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-gulf-mexico.* In case of problems accessing these documents, please call the contact listed below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Rachel Wachtendonk, Office of

Protected Resources, NMFS, (301) 427–8401, *wachtendonk.itp@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

On January 19, 2021, we issued a final rule with regulations to govern the unintentional taking of marine mammals incidental to geophysical survey activities conducted by oil and gas industry operators, and those persons authorized to conduct activities on their behalf (collectively ''industry operators''), in U.S. waters of the GOM over the course of 5 years (see 86 FR 5322, January 19, 2021). The rule was based on our findings that the total taking from the specified activities over the 5-year period will have a negligible impact on the affected species or stock(s) of marine mammals and will not have an unmitigable adverse impact on the availability of those species or stocks for subsistence uses. The rule became effective on April 19, 2021.

Our regulations at 50 CFR 217.180 allow for the issuance of LOAs to industry operators for the incidental take of marine mammals during geophysical survey activities and 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 (often referred to as mitigation), as well as requirements pertaining to the monitoring and reporting of such taking. Under 50 CFR 217.186(e), issuance of an LOA shall be based on a determination that the level of taking will be consistent with the findings made for the total taking allowable under these regulations and a determination that the amount of take authorized under the LOA is of no more than small numbers.

Summary of Request and Analysis

WesternGeco plans to conduct a three-dimensional (3D) ocean bottom node (OBN) survey over Walker Ridge and Green Canyon areas, with approximate water depths ranging from approximately 700 to 3,000 meters (m). WesternGeco anticipates using a single dual source vessel, either towing airgun array sources consisting of 28 elements, with a total volume of 5,240 cubic inches (in^3; 0.086 cubic meters (m^3)), or a Gemini enhanced frequency source (EFS) array. Please see WesternGeco's LOA application for additional detail.

The Gemini source operates on the same basic principles as a traditional airgun source in that it uses compressed air to create a bubble in the water column, which then goes through a series of collapses and expansions creating primarily low-frequency sounds. However, the Gemini source consists of one physical element with two large chambers of 4,000 in^3 (0.066 m^3) each (total volume of 8,000 in^3 (0.131 m^3)). This creates a larger bubble resulting in more of the energy being concentrated in low frequencies, with a fundamental frequency of 3.7 hertz. In addition to concentrating energy at lower frequencies, the Gemini source is expected to produce lower overall sound levels than the conventional airgun proxy source. The number of airguns in an array is highly influential on overall sound energy output, because the output increases approximately linearly with the number of airgun elements. In this case, because the same air volume is used to operate two very large guns, rather than tens of smaller guns, the array produces lower sound levels than a conventional array of equivalent total volume. NMFS anticipates that take by Level B harassment associated with use of the Gemini source would be less than would occur for a similar survey instead using the modeled airgun array as a sound source. Please see prior notices (*e.g.,* 88 FR 72739, October 23, 2023) for additional detail regarding the Gemini source.

Consistent with the preamble to the final rule, the survey effort proposed by WesternGeco in its LOA request was used to develop LOA-specific take estimates based on the acoustic exposure modeling results described in the preamble (see 86 FR 5398, January 19, 2021). In order to generate the appropriate take number for authorization, the following information was considered: (1) survey type; (2) location (by modeling zone [1]); (3) number of days; and (4) season.[2] The acoustic exposure modeling performed in support of the rule provides 24-hour exposure estimates for each species, specific to each modeled survey type in each zone and season.

No 3D OBN surveys were included in the modeled survey types, and use of existing proxies (*i.e.,* two-dimensional (2D), 3D narrow-azimuth (NAZ), 3D wide-azimuth (WAZ), Coil) is generally conservative for use in evaluation of 3D OBN survey effort, largely due to the greater area covered by the modeled proxies. Summary descriptions of these modeled survey geometries are available in the preamble to the proposed rule (83 FR 29212, 29220, June 22, 2018). Coil was selected as the best available proxy survey type in this case because the spatial coverage of the planned survey is most similar to the coil survey pattern. The planned 3D OBN survey will involve a single source vessel sailing along closely spaced survey lines that are approximately 345 m apart and approximately 100 kilometers (km) in length. The coil survey pattern was assumed to cover approximately 144 kilometers squared (km^2) per day (compared with approximately 795 km^2, 199 km^2, and 845 km^2 per day for the 2D, 3D NAZ, and 3D WAZ survey patterns, respectively). Among the different parameters of the modeled survey patterns (*e.g.,* area covered, line spacing, number of sources, shot interval, total simulated pulses), NMFS considers area covered per day to be most influential on daily modeled exposures exceeding Level B harassment criteria. Although

[1] For purposes of acoustic exposure modeling, the GOM was divided into seven zones. Zone 1 is not included in the geographic scope of the rule.

[2] For purposes of acoustic exposure modeling, seasons include winter (December–March) and summer (April–November).

WesternGeco is not proposing to perform a survey using the coil geometry, its planned 3D OBN survey is expected to cover approximately 69 km^2 per day, meaning that the coil proxy is most representative of the effort planned by WesternGeco in terms of predicted Level B harassment exposures.

All available acoustic exposure modeling results assume use of a 72-element, 8,000 in^3 array. Thus, take numbers authorized through the LOA are considered conservative due to differences in the airgun array (28 elements, 5,240 in^3 or Gemini), as compared to the source modeled for the rule.

The survey will take place over approximately 65 days, with 43 days in Zone 5 and 22 days in Zone 7. Although WesternGeco plans to conduct all 65 survey days in the ''summer'' season, we have calculated estimated take numbers based on an assumption that the survey could occur in either season in order to accommodate any potential delay of survey dates.

For some species, take estimates based solely on the modeling yielded results that are not realistically likely to occur when considered in light of other relevant information available during the rulemaking process regarding marine mammal occurrence in the GOM. The approach used in the acoustic exposure modeling, in which seven modeling zones were defined over the U.S. GOM, necessarily averages fine-scale information about marine mammal distribution over the large area of each modeling zone. Thus, although the modeling conducted for the rule is a natural starting point for estimating take, the rule acknowledged that other information could be considered (see, *e.g.,* 86 FR 5322, 5442, January 19, 2021), discussing the need to provide flexibility and make efficient use of previous public and agency review of other information and identifying that additional public review is not necessary unless the model or inputs used differ substantively from those that were previously reviewed by NMFS and the public. For this survey, NMFS has other relevant information reviewed during the rulemaking that indicates use of the acoustic exposure modeling to generate a take estimate for Rice's whales and killer whales produces results inconsistent with what is known regarding its occurrence in the GOM. Accordingly, we have adjusted the calculated take estimates for these species as described below.

NMFS' final rule described a ''core habitat area'' for Rice's whales (formerly known as GOM Bryde's whales) [3] located in the northeastern GOM in waters between 100 and 400 m depth along the continental shelf break (Rosel *et al.,* 2016). However, whaling records suggest that Rice's whales historically had a broader distribution within similar habitat parameters throughout the GOM (Reeves *et al.,* 2011; Rosel and Wilcox, 2014). In addition, habitat-based density modeling has identified similar habitat (*i.e.,* approximately 100–400 m water depths along the continental shelf break) as being potential Rice's whale habitat (Roberts *et al.,* 2016; Garrison *et al.,* 2023), and Rice's whales have been detected within this depth band throughout the GOM (Soldevilla *et al.,* 2022, 2024). See discussion provided at, *e.g.,* 83 FR 29228, June 22, 2018; 83 FR 29280, June 22, 2018; 86 FR 5418, January 19, 2021.

Although Rice's whales may occur outside of the core habitat area, we expect that any such occurrence would be limited to the narrow band of suitable habitat described above (*i.e.,* 100–400 m) and that, based on the few available records, these occurrences would be rare. WesternGeco's planned activities will overlap this depth range, with approximately 3.6 percent of the area expected to be ensonified by the survey above root-mean-squared pressure received levels (RMS SPL) of 160 decibel (dB) (referenced to 1 micropascal (re 1 μPa)) overlapping the 100–400 m isobaths. Therefore, while we expect take of Rice's whale to be unlikely, there is some reasonable potential for take of Rice's whale to occur in association with this survey. However, NMFS' determination in reflection of the data discussed above, which informed the final rule, is that use of the generic acoustic exposure modeling results for Rice's whales would result in estimated take numbers that are inconsistent with the assumptions made in the rule regarding expected Rice's whale take (86 FR 5322, January 19, 2021).

Killer whales are the most rarely encountered species in the GOM, typically in deep waters of the central GOM (Roberts *et al.,* 2015; Maze-Foley and Mullin, 2006). The approach used in the acoustic exposure modeling, in which seven modeling zones were defined over the U.S. GOM, necessarily averages fine-scale information about marine mammal distribution over the large area of each modeling zone. NMFS has determined that the approach results in unrealistic projections regarding the likelihood of encountering killer whales.

As discussed in the final rule, the density models produced by Roberts *et al.* (2016) represent the output of models derived from multi-year observations and associated environmental parameters that incorporate corrections for detection bias. However, in the case of killer whales, the model is informed by few data, as indicated by the coefficient of variation associated with the abundance predicted by the model (0.41, the second-highest of any GOM species model; Roberts *et al.,* 2016). The model's authors noted the expected non-uniform distribution of this rarely-encountered species (as discussed above) and expressed that, due to the limited data available to inform the model, it ''should be viewed cautiously'' (Roberts *et al.,* 2015).

NOAA surveys in the GOM from 1992–2009 reported only 16 sightings of killer whales, with an additional 3 encounters during more recent survey effort from 2017–2018 (Waring *et al.,* 2013; *https://www.boem.gov/gommapps*). Two other species were also observed on fewer than 20 occasions during the 1992–2009 NOAA surveys (Fraser's dolphin and false killer whale [4]). However, observational data collected by protected species observers (PSOs) on industry geophysical survey vessels from 2002–2015 distinguish the killer whale in terms of rarity. During this period, killer whales were encountered on only 10 occasions, whereas the next most rarely encountered species (Fraser's dolphin) was recorded on 69 occasions (Barkaszi and Kelly, 2019). The false killer whale and pygmy killer whale were the next most rarely encountered species, with 110 records each. The killer whale was the species with the lowest detection frequency during each period over which PSO data were synthesized (2002–2008 and 2009–2015). This information qualitatively informed our rulemaking process, as discussed at 86 FR 5334 (January 19, 2021), and similarly informs our analysis here.

The rarity of encounters during seismic surveys is not likely to be the product of high bias on the probability of detection. Unlike certain cryptic species with high detection bias, such as *Kogia* spp. or beaked whales, or deep-diving species with high availability bias, such as beaked whales or sperm whales, killer whales are typically

[3] The final rule refers to the GOM Bryde's whale (*Balaenoptera edeni*). These whales were subsequently described as a new species, Rice's whale (*Balaenoptera ricei*) (Rosel *et al.,* 2021).

[4] However, note that these species have been observed over a greater range of water depths in the GOM than have killer whales.

available for detection when present and are easily observed. Roberts *et al.* (2015) stated that availability is not a major factor affecting detectability of killer whales from shipboard surveys, as they are not a particularly long-diving species. Baird *et al.* (2005) reported that mean dive durations for 41 fish-eating killer whales for dives greater than or equal to 1 minute in duration was 2.3–2.4 minutes, and Hooker *et al.* (2012) reported that killer whales spent 78 percent of their time at depths between 0–10 m. Similarly, Kvadsheim *et al.* (2012) reported data from a study of 4 killer whales, noting that the whales performed 20 times as many dives 1–30 m in depth than to deeper waters, with an average depth during those most common dives of approximately 3 m.

In summary, killer whales are the most rarely encountered species in the GOM and typically occur only in particularly deep water (>700 m). This survey would take place in deep waters that would overlap with depths in which killer whales typically occur. While this information is reflected through the density model informing the acoustic exposure modeling results, there is relatively high uncertainty associated with the model for this species, and the acoustic exposure modeling applies mean distribution data over areas where the species is in fact less likely to occur. NMFS' determination in reflection of the data discussed above, which informed the final rule, is that use of the generic acoustic exposure modeling results for killer whales will generally result in estimated take numbers that are inconsistent with the assumptions made in the rule regarding expected killer whale take (86 FR 5403, January 19, 2021).

In past authorizations, NMFS has often addressed situations involving the low likelihood of encountering a rare species, such as Rice's whales and killer whales in the GOM, through authorization of take of a single group of average size (*i.e.,* representing a single potential encounter). See 83 FR 63268, December 7, 2018. See also 86 FR 29090, May 28, 2021 and 85 FR 55645, September 9, 2020. For the reasons expressed above, NMFS determined that a single encounter of Rice's whales and killer whales are more likely than the model-generated estimates and has authorized take associated with a single group encounter (*i.e.,* up to two animals for Rice's whales and up to seven animals for killer whales).

Based on the results of our analysis, NMFS has determined that the level of taking expected for this survey and authorized through the LOA is consistent with the findings made for the total taking allowable under the regulations. See table 1 in this notice and table 9 of the rule (86 FR 5322, January 19, 2021).

Small Numbers Determination

Under the GOM rule, NMFS may not authorize incidental take of marine mammals in an LOA if it will exceed ''small numbers.'' In short, when an acceptable estimate of the individual marine mammals taken is available, if the estimated number of individual animals taken is up to, but not greater than, one-third of the best available abundance estimate, NMFS will determine that the numbers of marine mammals taken of a species or stock are small. For more information please see NMFS' discussion of the MMPA's small numbers requirement provided in the final rule (see 86 FR 5438, January 19, 2021).

The take numbers for authorization are determined as described above in the Summary of Request and Analysis section. Subsequently, the total incidents of harassment for each species are multiplied by scalar ratios to produce a derived product that better reflects the number of individuals likely to be taken within a survey (as compared to the total number of instances of take), accounting for the likelihood that some individual marine mammals may be taken on more than 1 day (see 86 FR 5404, January 19, 2021). The output of this scaling, where appropriate, is incorporated into adjusted total take estimates that are the basis for NMFS' small numbers determinations, as depicted in table 1.

This product is used by NMFS in making the necessary small numbers determinations through comparison with the best available abundance estimates (see discussion at 86 FR 5391, January 19, 2021). For this comparison, NMFS' approach is to use the maximum theoretical population, determined through review of current stock assessment reports (SAR; *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and model-predicted abundance information (*https://seamap.env.duke.edu/models/Duke/GOM/*). For the latter, for taxa where a density surface model could be produced, we use the maximum mean seasonal (*i.e.,* 3-month) abundance prediction for purposes of comparison as a precautionary smoothing of month-to-month fluctuations and in consideration of a corresponding lack of data in the literature regarding seasonal distribution of marine mammals in the GOM. Information supporting the small numbers determinations is provided in table 1.

TABLE 1—TAKE ANALYSIS

Species	Authorized take	Scaled take [1]	Abundance [2]	Percent abundance
Rice's whale [3]	2	n/a	51	7.0
Sperm whale	1,248	527.7	2,207	23.9
Kogia spp	[4] 493	149.2	4,373	4.1
Beaked whales	6,021	608.1	3,768	16.1
Rough-toothed dolphin	1,050	301.2	4,853	6.2
Bottlenose dolphin	4,072	1,168.7	176,108	0.7
Clymene dolphin	2,920	838.0	11,895	7.0
Atlantic spotted dolphin	1,625	466.2	74,785	0.6
Pantropical spotted dolphin	15,971	4,583.6	102,361	4.5
Spinner dolphin	3,054	876.6	25,114	3.5
Striped dolphin	1,206	346.0	5,229	6.6
Fraser's dolphin	354	101.5	1,665	6.1
Risso's dolphin	791	233.3	3,764	6.2
Melon-headed whale	1,912	564.1	7,003	8.1
Pygmy killer whale	532	156.9	2,126	7.4
False killer whale	773	228.1	3,204	7.1
Killer whale	7	n/a	267	3.4

TABLE 1—TAKE ANALYSIS—Continued

Species	Authorized take	Scaled take [1]	Abundance [2]	Percent abundance
Short-finned pilot whale	485	143.0	1,981	7.2

[1] Scalar ratios were applied to ''Authorized Take'' values as described at 86 FR 5322, 5404 (January 19, 2021) to derive scaled take numbers shown here.
[2] Best abundance estimate. For most taxa, the best abundance estimate for purposes of comparison with take estimates is considered here to be the model-predicted abundance (Roberts *et al.,* 2016). For those taxa where a density surface model predicting abundance by month was produced, the maximum mean seasonal abundance was used. For those taxa where abundance is not predicted by month, only mean annual abundance is available. For Rice's whale and killer whale, the larger estimated SAR abundance estimate is used.
[3] The final rule refers to the GOM Bryde's whale (*Balaenoptera edeni*). These whales were subsequently described as a new species, Rice's whale (*Balaenoptera ricei*) (Rosel *et al.,* 2021).
[4] Includes 28 takes by Level A harassment and 465 takes by Level B harassment. Scalar ratio is applied to takes by Level B harassment only; small numbers determination made on basis of scaled Level B harassment take plus authorized Level A harassment take.

Based on the analysis contained herein of WesternGeco's proposed survey activity described in its LOA application and the anticipated take of marine mammals, NMFS finds that small numbers of marine mammals will be taken relative to the affected species or stock sizes (*i.e.,* less than one-third of the best available abundance estimate) and therefore the taking is of no more than small numbers.

Authorization

NMFS has determined that the level of taking for this LOA request is consistent with the findings made for the total taking allowable under the incidental take regulations and that the amount of take authorized under the LOA is of no more than small numbers. Accordingly, we have issued an LOA to WesternGeco authorizing the take of marine mammals incidental to its geophysical survey activity, as described above.

Dated: March 28, 2024.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2024–07138 Filed 4–4–24; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD680]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Exempted Fishing Permits

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

ACTION: Notice of receipt of an application for exempted fishing permit; request for comments.

SUMMARY: NMFS announces the receipt of an application for an exempted fishing permit (EFP) from LGL Ecological Research Associates Inc. If granted, the EFP would allow the retention, up to 24 hours, and lethal harvest of a limited number of red drum, king mackerel, and Spanish mackerel harvested by approved participants in the Louisiana commercial menhaden purse seine fishery in Federal waters during the 2024 menhaden season. The project would seek to quantify bycatch and test post-release mortality of these species in the fishery to assess impacts the fishery may have on Federally-managed species in the Gulf of Mexico (Gulf).

DATES: Written comments must be received on or before April 22, 2024.

ADDRESSES: You may submit comments on the application, identified by ''NOAA–NMFS–2024–0048'', by any of the following methods:

Electronic Submission: Submit all electronic public comments via the Federal e-Rulemaking Portal. Visit *https://www.regulations.gov* and type ''NOAA–NMFS–2024–0048'' in the Search box. Click the ''Comment'' icon, complete the required fields, and enter or attach your comments.

Mail: Submit written comments to Dan Luers, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *https://www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, *etc.*), 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 EFP application may be obtained from the Southeast Regional Office website at *https://www.fisheries.noaa.gov/southeast/bycatch/exempted-fishing-permit-quantification-bycatch-composition-and-survival/.*

FOR FURTHER INFORMATION CONTACT: Dan Luers, 727–824–5305, *Daniel.Luers@noaa.gov.*

SUPPLEMENTARY INFORMATION: The EFP is requested under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C 1801 *et seq.*), and regulations at 50 CFR 600.745(b) concerning exempted fishing.

Red drum, king mackerel, and Spanish mackerel are Federally-managed species that occur in Gulf waters that are caught as bycatch in the Louisiana commercial menhaden purse seine fishery, which operates in state and Federal waters. The proposed research would quantify bycatch from the Louisiana menhaden purse seine fishery as they occur in purse seine nets, fish excluder grates, dewatering screens, and release chutes, with the goal of quantifying bycatch for each exclusion method within the fishery and evaluate the post-release mortality of red drum, king mackerel, and Spanish mackerel caught as bycatch by the fishery.

Approximately 400 purse seine sets are expected to occur during the 2024 menhaden purse seine season (April 15–November 1, 2024) in water depths less than 60 feet (18 meters). During fishing operations, the applicant would accompany 1 of the 53 state-permitted vessels, which deploys a 1,200 to 1,500 foot (366 to 457 meters) purse seine for a soak time of 20 to 45 minutes and a second vessel pumps the catch (catch-collecting vessel) from the net into the hold. In this project, researchers on board the catch-collecting vessel would record bycatch caught by each exclusion method described in the previous paragraph. Off Louisiana, the commercial harvest of menhaden is

restricted to waters seaward of a boundary line described in the states' statutes (Louisiana Title 76) and includes both state and some Federal waters. The majority of fishing activities under this EFP are expected to occur in Louisiana State waters, but fishing operations could occur in Federal waters as the menhaden migrate from inshore estuarine waters to offshore marine waters in October. NMFS estimates that 64 of the 400 sets anticipated for the 2024 menhaden season could occur in Federal waters.

The EFP would allow the applicant to harvest up to 200 individuals each of red drum, king mackerel, and Spanish mackerel during the 2024 menhaden season to determine sex ratios. An additional number of red drum, king mackerel, and Spanish mackerel (up to 400 per species) would be held for 24 hours in tanks with continuous water flow on board the catch-collecting vessel to assess short-term survival and then would be tagged and released. All other bycatch initially retained by the applicant would be returned to the water. Red drum, king mackerel, and Spanish mackerel that die during normal fishing operations, or that die in the survival study, would be preferentially biopsied to minimize mortality attributed to this study. No red drum, king mackerel, and Spanish mackerel landed as part of the project would be sold.

Federal regulations at 50 CFR 622.92(b) prohibit the harvest and possession of red drum in or from the Gulf Federal waters and any red drum caught in the Gulf Federal waters must be released immediately with a minimum of harm. The EFP would allow the applicant to biopsy up to 200 red drum and possess for up to 24 hours an additional 400 red drum during the 2024 menhaden purse seine season (April 15–November 1, 2024).

Federal regulations at 50 CFR 622.375(a)(1)(iv) and 622.375(b)(3) prohibit the harvest of king mackerel and Spanish mackerel by purse seine gear. Additionally, regulations at 50 CFR 622.380(b) prohibit possession of king mackerel less than 24 inches (61 cm), fork length, and 622.380(c) prohibit possession of Spanish mackerel less than 12 inches (30.5 cm), fork length. The EFP would allow the applicant to biopsy up to 200 of each species, including undersized fish, and possess for up to 24 hours an additional 400 each of king mackerel and Spanish mackerel and using purse seine gear during the 2024 menhaden purse seine season.

If granted, the EFP would be effective from April 15, 2024, through December 31, 2024. The applicant and commercial menhaden fishermen and vessels participating in the EFP must comply with all other applicable laws and regulations.

NMFS finds the application warrants further consideration based on a preliminary review. At its January 2024 meeting, the Gulf of Mexico Fishery Management Council reviewed the application and recommended that NMFS issue the EFP. A final decision on issuance of the EFP will depend on NMFS' review of public comments received on the application, consultations with the appropriate fishery management agencies of the affected states, and the U.S. Coast Guard, and a determination that the activities to be taken under the EFP are consistent with all other applicable laws.

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

Dated: April 2, 2024.

Everett Wayne Baxter,

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

[FR Doc. 2024–07304 Filed 4–4–24; 8:45 am]

BILLING CODE 3510–22–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; Northwest Region, Pacific Coast Groundfish Fishery: Trawl Rationalization Cost Recovery Program

The Department of Commerce will submit 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, on or after the date of publication of this notice. We invite 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. Public comments were previously requested via the **Federal Register** on August 22, 2023 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic & Atmospheric Administration (NOAA), Commerce.

Title: Northwest Region, Pacific Coast Groundfish Fishery: Trawl Rationalization Cost Recovery Program.

OMB Control Number: 0648–0663.

Form Number(s): None.

Type of Request: Regular submission; revision of a current information collection.

Number of Respondents: 580.

Average Hours per Response: Cost recovery fee forms: 1 hour.

Total Annual Burden Hours: 580.

Needs and Uses: This request is for a revision of a currently approved information collection includes the collection of electronic fish ticket numbers on the Shorebased Individual Fishing Quota Program's payment form. The Magnuson-Stevens Fishery Conservation and Management Act (MSA) authorizes and requires that the Secretary of Commerce maintain a cost recovery program to cover part of the management, data collection and analysis, and enforcement costs of the limited access privilege programs, such as the Pacific Coast Groundfish Trawl Rationalization Program (Trawl Program). Cost recovery fees may not exceed three percent of the ex-vessel value. The Trawl Program cost recovery program requires fish sellers to submit fees to fish buyers who then submit those fees to NOAA's National Marine Fisheries Service (NMFS). Fish buyers must also submit information to NMFS on the volume and value of harvested groundfish when submitting the fees. Information is collected from monthly and annual reports as well as non-payment documents when necessary.

The information collected is used to track the payment of cost recovery fees, reconcile cost recovery payments with landings data from other sources, calculate average ex-vessel values, and, if necessary, help in the resolution of non-payment issues. The addition of a requirement to record electronic fish ticket numbers corresponding to cost recovery payments will aid in this reconciliation process.

This program is authorized under the Pacific coast groundfish fishery regulations, trawl rationalization cost recovery program at 50 CFR 660.115.

Affected Public: Business or other for-profit organizations.

Frequency: Monthly and annually.

Respondent's Obligation: Mandatory.

Legal Authority: NMFS and the Pacific Fisheries Management Council (Council) manage the groundfish fisheries in the exclusive economic zone seaward of California, Oregon, and Washington under the Pacific Coast Groundfish Fishery Management Plan (FMP). The Council prepared the FMP under the authority of the MSA, 16

U.S.C. 1801 *et seq.* Regulations governing United States fisheries and implementing the FMP appear at 50 CFR part 660.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0648–0663.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–07238 Filed 4–4–24; 8:45 am]

BILLING CODE 3510–22–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; Individual Fishing Quotas for Pacific Halibut and Sablefish in the Alaska Fisheries

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 June 4, 2024.

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 0648–0272 in the subject line of your comments. 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 Gabrielle Aberle, National Marine Fisheries Service, P.O. Box 21668, Juneau, AK 99802–1668, (323) 372–0062, *gabrielle.aberle@noaa.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

The National Marine Fisheries Service (NMFS), Alaska Regional Office, is requesting renewal of this currently approved information collection that contains requirements for the Pacific Halibut and Sablefish Individual Fishing Quota Program (IFQ Program).

Commercial halibut and sablefish fisheries in the Gulf of Alaska and Bering Sea and Aleutian Islands are managed primarily under the IFQ Program. The IFQ Program is managed under the authority of the Northern Pacific Halibut Act of 1982 (16 U.S.C. 773c; Halibut Act), with respect to Pacific halibut, and the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.;* Magnuson-Stevens Act), with respect to sablefish. Regulations implementing the IFQ Program are set forth at 50 CFR part 679.

A key objective of the IFQ Program is to support the social and economic character of the fisheries and coastal fishing communities where many of these fisheries are based. Participation in the IFQ Program is limited to persons that hold quota share (QS), although there are several very limited provisions for ''leasing'' of annual IFQ. QS is a transferable permit that was initially issued to persons who owned or leased vessels that made legal commercial fixed-gear landings of Pacific halibut or sablefish in the waters off Alaska from 1988 through 1990.

NMFS annually issues eligible QS holders an IFQ fishing permit that authorizes participation in the IFQ fisheries. Those to whom IFQ permits are issued may harvest their annual allocation at any time during the eight plus-month IFQ halibut and sablefish seasons.

More information on the IFQ Program is provided on the NMFS Alaska Region website at *https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/pacific-halibut-and-sablefish-individual-fishing-quota-ifq-program.*

Some of the collection instruments in this information collection are used by participants in the Western Alaska Community Development Quota (CDQ) Program. The purpose of the CDQ Program is to provide eligible western Alaska villages with the opportunity to participate and invest in fisheries in the Bering Sea and Aleutian Islands Management Area (BSAI); to support economic development in western Alaska; to alleviate poverty and provide economic and social benefits for residents of western Alaska; and to achieve sustainable and diversified local economies in western Alaska. In fitting with these goals, NMFS allocates a portion of the annual catch limits for a variety of commercially valuable marine species in the BSAI to the CDQ Program. Pacific halibut is one of these species. More information on the CDQ Program is provided on the NMFS Alaska Region website at *https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/community-development-quota-cdq-program.* Information collection requirements for the CDQ Program are also approved under OMB Control Number 0648–0269.

This information collection for the IFQ Program is required to manage commercial halibut and sablefish fishing under the Magnuson-Stevens Act, the Halibut Act, and under 50 CFR parts 300 and 679.

This information collection contains the forms used by participants in the IFQ Program to apply for, renew, or replace permits; transfer or lease IFQ and QS; determine compliance with IFQ program requirements; and designate a beneficiary for a QS holder. Two of the permit applications are also used by participants in the CDQ Program. This information collection also contains annual reports and other collections submitted by telephone or other methods and that do not have forms.

The type of information collected includes information on the applicants, transferors, transferees, permits, IFQ or QS types and owners, beneficiaries, vessels, business operations, medical declarations, landings, gear types, products, and harvests and harvest areas.

This information is used to identify and authorize participants in the halibut and sablefish fisheries, to track and transfer quota share, to limit transfers to authorized participants, and to monitor quota share balances and harvest in these fisheries.

II. Method of Collection

The information is collected primarily by mail, delivery, fax, email, telephone, or eFISH. eFISH is the NMFS Alaska

Region online Fisheries Information System. The forms and applications are available as fillable pdfs on the NMFS Alaska Region website at *https://www.fisheries.noaa.gov/permit/alaska-ifq-halibut-sablefish-and-cdq-halibut-program-fishery-applications-and-reporting.*

III. Data

OMB Control Number: 0648–0272.

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.

Estimated Number of Respondents: 3,441.

Estimated Time per Response: Application for IFQ/CDQ Hired Master Permit, 1 hour; Application for IFQ/CDQ Registered Buyer Permit, 30 minutes; Application for Replacement of Certificates or Permits, 30 minutes; Application for Eligibility to Receive QS/IFQ by Transfer, 2 hours; QS Holder: Identification of Ownership Interest, 2 hours; Application for Transfer of QS, 2 hours; Application for Transfer of QS/IFQ by Self Sweep Up, 2 hours; Application for Medical Transfer of IFQ, 1.5 hours; Application for Temporary Transfer of Halibut/Sablefish IFQ, 2 hours; (emergency) Application for Temporary Transfer of Halibut/Sablefish IFQ, 2 hours; Annual Report for CDQ IFQ Transfers, 40 hours; QS/IFQ Beneficiary Designation Form, 30 minutes; Appeals, 4 hours; IFQ Administrative Waiver, 6 minutes; Prior Notice of Landing, 15 minutes; IFQ Departure Report, 15 minutes; Transshipment Authorization, 12 minutes; Dockside sales, 6 minutes; Application for a Non-profit Corporation to be Designated as a Recreational Quota Entity, 200 hours; Application for Transfer of Quota Share To or From a Recreational Quota Entity, 2 hours; Recreational Quota Entity Annual Report, 40 hours.

Estimated Total Annual Burden Hours: 11,236 hours.

Estimated Total Annual Cost to Public: $28,225 in recordkeeping and reporting costs.

Respondent's Obligation: Voluntary, Required to Obtain or Retain Benefits, Mandatory.

Legal Authority: Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1801 *et seq.;* Northern Pacific Halibut Act of 1982, 16 U.S.C. 773c.

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 ICR. 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,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–07239 Filed 4–4–24; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Deletions from the Procurement List.

SUMMARY: This action deletes product(s) and service(s) from the Procurement List that were furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Date added to and deleted from the Procurement List:* May 5, 2024.

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: Michael R. Jurkowski, Telephone: (703) 489–1322, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Deletions

On 3/1/2024, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List. This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3.

After consideration of the relevant matter presented, the Committee has determined that the product(s) and service(s) listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the product(s) and service(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the product(s) and service(s) deleted from the Procurement List.

End of Certification

Accordingly, the following product(s) and service(s) are deleted from the Procurement List:

Product(s)

NSN(s)—Product Name(s):
5350–00–187–6272—Cloth, Abrasive, Aluminum-oxide, 100 Grit, Jean Back, Grey, 50 Yard, 1″, BX/10
5350–00–187–6283—Cloth, Abrasive, Aluminum-oxide, 100 Grit, Jean Back, Grey, 50 Yard, 1½″, BX/10
5350–00–187–6281—Cloth, Abrasive, Aluminum-oxide, 150 Grit, Jean Back, Grey, 50 Yard, 1½″, BX/10
5350–00–229–3080—Cloth, Abrasive, Aluminum-oxide, 240 Grit, Jean Back, Grey, 50 Yard, 3″, BX/10
5350–00–229–3094—Cloth, Abrasive, Aluminum-oxide, 150 Grit, Jean Back, Grey, 50 Yard, 3″

Authorized Source of Supply: Louisiana Association for the Blind, Shreveport, LA

Contracting Activity: GSA/FSS GREATER SOUTHWEST ACQUISITI, FORT

WORTH, TX

NSN(s)—Product Name(s):

8410–01–456–5800—Slacks, Dress, Navy, Women's, Blue, 18JR
8410–01–456–5766—Slacks, Dress, Navy, Women's, Blue, 22WT
8410–01–456–5769—Slacks, Dress, Navy, Women's, Blue, 24JP
8410–01–456–5780—Slacks, Dress, Navy, Women's, Blue, 18JP
8410–01–456–5771—Slacks, Dress, Navy, Women's, Blue, 24JR
8410–01–456–5774—Slacks, Dress, Navy, Women's, Blue, 24P
8410–01–456–5784—Slacks, Dress, Navy, Women's, Blue, 24WR
8410–01–456–5786—Slacks, Dress, Navy, Women's, Blue, 24WT
8410–01–456–5790—Slacks, Dress, Navy, Women's, Blue, 26JP
8410–01–456–5794—Slacks, Dress, Navy, Women's, Blue, 26JR
8410–01–456–5803—Slacks, Dress, Navy, Women's, Blue, 18WT
8410–01–456–5806—Slacks, Dress, Navy, Women's, Blue, 20JP
8410–01–456–5808—Slacks, Dress, Navy, Women's, Blue, 20JR
8410–01–456–5809—Slacks, Dress, Navy, Women's, Blue, 20P
8410–01–456–5812—Slacks, Dress, Navy, Women's, Blue, 20WT
8410–01–456–5814—Slacks, Dress, Navy, Women's, Blue, 22JP
8410–01–456–5815—Slacks, Dress, Navy, Women's, Blue, 22JR
8410–01–456–5817—Slacks, Dress, Navy, Women's, Blue, 22P
8410–01–456–5820—Slacks, Dress, Navy, Women's, Blue, 22R
8410–01–456–6281—Slacks, Dress, Navy, Women's, Blue, 26MP
8410–01–456–6286—Slacks, Dress, Navy, Women's, Blue, 26R
8410–01–456–6290—Slacks, Dress, Navy, Women's, Blue, 26MT
8410–01–456–6292—Slacks, Dress, Navy, Women's, Blue, 26WR
8410–01–456–6295—Slacks, Dress, Navy, Women's, Blue, 26WT
8410–01–456–6302—Slacks, Dress, Navy, Women's, Blue, 22MT
8410–00–0SL–K608—Slacks, Dress, Navy, Women's, Blue, Special Measurement
8410–01–373–4404—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 4P
8410–01–373–4405—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 6MP
8410–01–373–4406—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 6WP
8410–01–373–4407—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 6WR
8410–01–373–4408—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 8P
8410–01–373–4409—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 8MT
8410–01–373–4410—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 8WP
8410–01–373–4411—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 8WR
8410–01–375–4827—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 10WT
8410–01–375–4828—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 12JP
8410–01–375–4829—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 12JR
8410–01–375–4830—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 12P
8410–01–375–4831—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 12T
8410–01–375–4832—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 12WP
8410–01–375–4833—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 12WR
8410–01–375–4834—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 12WT
8410–01–375–4835—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 14JP
8410–01–375–4836—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 14JR
8410–01–375–4837—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 14JT
8410–01–375–4838—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 14P
8410–01–375–4839—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 14T
8410–01–375–4840—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 14WP
8410–01–375–4841—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 14WR
8410–01–375–4842—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 14WT
8410–01–375–4843—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 16JP
8410–01–375–4844—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 16JR
8410–01–375–4845—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 16P
8410–01–375–4846—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 16T
8410–01–375–4847—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 16WR
8410–01–375–4848—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 16WT
8410–01–375–4849—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 18P
8410–01–375–4850—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 18T
8410–01–375–4851—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 18WR
8410–01–375–4852—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 4R
8410–01–375–4853—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 6MR
8410–01–375–4854—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 8MR
8410–01–375–4855—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 10R
8410–01–375–4856—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 12R
8410–01–375–4857—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 14R
8410–01–375–4858—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 16R
8410–01–375–4859—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 18R
8410–01–375–4860—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 20MR
8410–01–377–9378—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 10WR
8410–01–377–9434—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 10JR
8410–01–377–9508—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 10T
8410–01–377–9717—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 10WP
8410–01–377–9737—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 10JP
8410–01–377–9791—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 10JT
8410–01–377–9799—Slacks, Commissioned and Enlisted, Navy, Women's, Blue, 10P
8410–01–456–5779—Slacks, Dress, Navy, Women's, Blue, 24 Misses Regular
8410–01–456–5781—Slacks, Dress, Navy, Women's, Blue, 24 Misses Tall
8410–01–456–5810—Slacks, Dress, Navy, Women's, Blue, 20 Misses Tall
8410–01–456–5811—Slacks, Dress, Navy, Women's, Blue, 20 Women's Regular
8410–01–456–6306—Slacks, Dress, Navy, Women's, Blue, 22 Women's Regular

Contracting Activity: DLA TROOP SUPPORT, PHILADELPHIA, PA

NSN(s)—Product Name(s):

7210–00–259–9006—Pillowcase, Cotton/Polyester, White, 20½″ x 32½″

Authorized Source of Supply: The Lighthouse for the Blind in New Orleans, Inc., New Orleans, LA

Contracting Activity: GSA/FSS GREATER SOUTHWEST ACQUISITI, FORT WORTH, TX

Service(s)

Service Type: Furniture Design and Configuration Services

Mandatory for: Rhode Island National Guard, 330 Camp Street, Providence, RI
Authorized Source of Supply: Industries for the Blind and Visually Impaired, Inc., West Allis, WI
Contracting Activity: DEPT OF THE ARMY, W7NY USPFO ACTIVITY RI ARNG

Michael R. Jurkowski,

Director, Business Operations.

[FR Doc. 2024–07260 Filed 4–4–24; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF EDUCATION

Annual Updates to the Income-Contingent Repayment (ICR) Plan Formula for 2024—William D. Ford Federal Direct Loan Program

AGENCY: Federal Student Aid, Department of Education.

ACTION: Notice.

SUMMARY: The Secretary announces the annual updates to the ICR plan formula for 2024 to give notice to borrowers and the public regarding how monthly ICR payment amounts will be calculated for the 2024–2025 year under the William D. Ford Federal Direct Loan (Direct Loan) Program, Assistance Listing Number 84.063.

DATES: The adjustments to the income percentage factors for the ICR plan formula contained in this notice are applicable from July 1, 2024, to June 30, 2025, for any borrower who enters the ICR plan or has a monthly payment amount under the ICR plan recalculated during that period.

FOR FURTHER INFORMATION CONTACT: Travis Sturlaugson, U.S. Department of Education, 830 First Street NE, Washington, DC 20202. Telephone: (202) 377–4174. Email: *travis.sturlaugson@ed.gov.*

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION: Effective July 1, 2024, borrowers may select the ICR plan only for repayment of non-defaulted Direct Consolidation Loans that repaid one or more Direct or Federal PLUS Loans made to a parent borrower. However, borrowers who were repaying other types of Direct Loans under the ICR plan as of July 1, 2024, may continue to repay their loans under that plan. Under the ICR plan, the borrower's monthly payment amount is based on the borrower's Adjusted Gross Income (AGI), family size, loan amount, and the interest rate applicable to each of the borrower's loans.

A Direct Loan borrower who repays under the ICR plan pays the lesser of: (1) the monthly amount that would be required over a 12-year repayment period with fixed payments, multiplied by an income percentage factor; or (2) 20 percent of their discretionary income.

We adjust the income percentage factors annually to reflect changes in inflation and announce the adjusted factors in the **Federal Register**, as required by 34 CFR 685.209(b)(1)(ii)(A). We use the adjusted income percentage factors to calculate a borrower's monthly ICR payment amount when the borrower initially applies for the ICR plan or when the borrower submits annual income documentation, as required under the ICR plan. This notice contains the adjusted income percentage factors for 2024, examples of how the monthly ICR payment amount is calculated, and charts showing sample repayment amounts based on the adjusted ICR plan formula. This information is included in the following three attachments:

- *Attachment 1—Income Percentage Factors for 2024*
- *Attachment 2—Examples of the Calculations of Monthly Repayment Amounts*
- *Attachment 3—Charts Showing Sample ICR Repayment Amounts for Single and Married Borrowers*

In Attachment 1, to reflect changes in inflation, we updated the income percentage factors that were published in the **Federal Register** on April 26, 2023 (88 FR 25388). Specifically, we have revised the table of income percentage factors by changing the dollar amounts of the incomes shown by a percentage equal to the estimated percentage change between the not-seasonally-adjusted Consumer Price Index for all urban consumers for December 2023 and December 2024.

The income percentage factors reflected in Attachment 1 may cause a borrower's payments to be lower than they were in prior years, even if the borrower's income is the same as in the prior year. The revised repayment amount more accurately reflects the impact of inflation on the borrower's current ability to repay.

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site, you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at this site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Program Authority: 20 U.S.C. 1087 *et seq.*

Richard Cordray,

Chief Operating Officer, Federal Student Aid.

Attachment 1—Income Percentage Factors for 2024

INCOME PERCENTAGE FACTORS FOR 2024

Single		Married/head of household	
AGI	Percent factor	AGI	Percent factor
$13,736	55.00	$13,736	50.52
$18,900	57.79	$21,672	56.68
$24,319	60.57	$25,826	59.56
$29,861	66.23	$33,764	67.79
$35,153	71.89	$41,828	75.22
$41,828	80.33	$52,536	87.61
$52,536	88.77	$65,889	100.00
$65,890	100.00	$79,249	100.00

INCOME PERCENTAGE FACTORS FOR 2024—Continued

Single		Married/head of household	
AGI	Percent factor	AGI	Percent factor
$79,249	100.00	$99,285	109.40
$95,245	111.80	$132,667	125.00
$121,958	123.50	$179,409	140.60
$172,734	141.20	$250,911	150.00
$198,056	150.00	$410,007	200.00
$352,771	200.00		

Attachment 2—Examples of the Calculations of Monthly Repayment Amounts

General notes about the examples in this attachment:

- We have a calculator that borrowers can use to estimate what their payment amounts would be under the ICR plan. The calculator is called the ''Loan Simulator'' and is available at *studentaid.gov/loan-simulator.* Based on information entered into the calculator by the borrower (for example, income, family size, and tax filing status), this calculator provides a detailed, individualized assessment of a borrower's loans and repayment plan options, including the ICR plan.
- The interest rates used in the examples are for illustration only. The actual interest rates on an individual borrower's Direct Loans depend on the loan type and when the loan was first disbursed.
- The Poverty Guideline amounts used in the examples are from the 2024 U.S. Department of Health and Human Services (HHS) Poverty Guidelines for the 48 contiguous States and the District of Columbia. Different Poverty Guidelines apply to residents of Alaska and Hawaii. The Poverty Guidelines for 2024 were published in the **Federal Register** on January 17, 2024 (89 FR 2961).
- All of the examples use an income percentage factor corresponding to an adjusted gross income (AGI) in the table in Attachment 1. If an AGI is not listed in the income percentage factors table in Attachment 1, the applicable income percentage can be calculated by following the instructions under the ''Interpolation'' heading later in this attachment.
- Married borrowers may repay their Direct Loans jointly under the ICR plan if both spouses have loans eligible for the ICR plan. If a married couple elects this option, we determine a joint ICR payment amount based on the combined outstanding balances of each borrower's Direct Loans and the combined AGIs of both borrowers. We then prorate the joint payment amount for each borrower based on the proportion of that borrower's debt to the total outstanding balance. We bill each borrower separately.
- For example, if a married couple, John and Briana, has a total outstanding Direct Loan debt of $60,000 that is eligible for repayment under the ICR plan, of which $40,000 belongs to John and $20,000 to Briana, we would apportion 67 percent of the monthly ICR payment to John and the remaining 33 percent to Briana. To take advantage of a joint ICR payment, married couples need not file taxes jointly; they may file separately and subsequently provide the other spouse's tax information to the borrower's Federal loan servicer.

Calculating the monthly payment amount using a standard amortization and a 12-year repayment period.

The formula to amortize a loan with a standard schedule (in which each payment is the same over the course of the repayment period) is as follows:

$$M = P \times < (I \div 12) \div [1 - \{1 + (I \div 12)\} \wedge - N] >$$

In the formula—

- M is the monthly payment amount;
- P is the outstanding principal and interest balance of the loan at the time the loan entered repayment;
- I is the annual interest rate on the loan, expressed as a decimal (for example, for a loan with an interest rate of 6 percent, 0.06); and
- N is the total number of months in the repayment period (for example, for a loan with a 12-year repayment period, 144 months).

For example, assume that Billy has a $10,000 Direct Loan that is eligible for repayment under the ICR plan with an interest rate of 6 percent.

Step 1: To solve for M, first simplify the numerator of the fraction by which we multiply P, the outstanding principal balance. To do this divide I (the interest rate expressed as a decimal) by 12. In this example, Billy's interest rate is 6 percent. As a decimal, 6 percent is 0.06.

- $0.06 \div 12 = 0.005$

Step 2: Next, simplify the denominator of the fraction by which we multiply P. To do this divide I (the interest rate expressed as a decimal) by 12. Then, add one. Next, raise the sum of the two figures to the negative power that corresponds to the length of the repayment period in months. In this example, because we are amortizing a loan to calculate the monthly payment amount under the ICR plan, the applicable figure is 12 years, which is 144 months. Finally, subtract the result from one.

- $0.06 \div 12 = 0.005$
- $1 + 0.005 = 1.005$
- $1.005 \wedge -144 = 0.48762628$
- $1 - 0.48762628 = 0.51237372$

Step 3: Next, resolve the fraction by dividing the result from Step 1 by the result from Step 2.

- $0.005 \div 0.51237372 = 0.0097585$

Step 4: Finally, solve for M, the monthly payment amount, by multiplying the outstanding principal balance of the loan by the result of Step 3.

- $\$10,000 \times 0.0097585 = \$97.59$

The remainder of the examples in this attachment will only show the results of the formula. In each of the examples, the Direct Loan amounts represent the outstanding principal balance at the time the loans entered repayment.

Example 1. Kesha is single with no dependents and has $15,000 in Direct Loans that are eligible for repayment under the ICR plan. The interest rate on Kesha's loans is 6 percent, and she has an AGI of $35,153.

Step 1: Determine the total monthly payment amount based on what Kesha would pay over 12 years using standard amortization. To do this, use the formula that precedes Example 1. In this example, the monthly payment amount would be $146.38.

Step 2: Multiply the result of Step 1 by the income percentage factor shown in the income percentage factors table (see Attachment 1 to this notice) that corresponds to Kesha's AGI. In this example, an AGI of $35,153 corresponds to an income percentage factor of 71.89 percent.

- $0.7189 \times \$146.38 = \$105.23$

Step 3: Now, determine the monthly payment amount equal to 20 percent of Kesha's discretionary income (discretionary income is AGI minus the HHS Poverty Guideline amount for a borrower's family size and State of residence). To do this, subtract the HHS Poverty Guideline amount for a family of one from Kesha's AGI, multiply the result by 20 percent, and then divide by 12:

- $35,153 − $15,060 = $20,093
- $20,093 × 0.20 = $4,018.60
- $4,018.60 ÷ 12 = $334.88

Step 4: Compare the amount from Step 2 with the amount from Step 3. In this example, Kesha would pay the amount calculated under Step 2 ($105.23), since this is the lesser of the two payment amounts.

Example 2. Paul is married to Jesse and they have no dependents. They file their Federal income tax return jointly. Paul has a Direct Loan balance of $10,000, and Jesse has a Direct Loan balance of $15,000. Both of their Direct Loans are eligible for repayment under the ICR plan and have an interest rate of 6 percent.

Paul and Jesse have a combined AGI of $99,285 and are repaying their loans jointly under the ICR plan (for general information regarding joint ICR payments for married couples, see the fifth and sixth bullets under the heading ''General notes about the examples in this attachment'').

Step 1: Add Paul's and Jesse's Direct Loan balances to determine their combined aggregate loan balance:

- $10,000 + $15,000 = $25,000

Step 2: Determine the combined monthly payment amount for Paul and Jesse based on what both borrowers would pay over 12 years using standard amortization. To do this, use the formula that precedes Example 1. In this example, their combined monthly payment amount would be $243.96.

Step 3: Multiply the result of Step 2 by the income percentage factor shown in the income percentage factors table (see Attachment 1 to this notice) that corresponds to Paul and Jesse's combined AGI. In this example, the combined AGI of $99,285 corresponds to an income percentage factor of 109.40 percent.

- 1.094 × $243.96 = $266.90

Step 4: Now, determine the monthly payment amount equal to 20 percent of Paul and Jesse's combined discretionary income (discretionary income is AGI minus the HHS Poverty Guideline amount for a borrower's family size and State of residence). To do this, subtract the Poverty Guideline amount for a family of two from the combined AGI, multiply the result by 20 percent, and then divide by 12:

- $99,285 − $20,440 = $78,845
- $78,845 × 0.20 = $15,769
- $15,769 ÷ 12 = $1,314.08

Step 5: Compare the amount from Step 3 with the amount from Step 4. Paul and Jesse would jointly pay the amount calculated under Step 3 ($266.90), since this is the lesser of the two amounts.

Step 6: Because Paul and Jesse are jointly repaying their Direct Loans under the ICR plan, the monthly payment amount calculated under Step 5 applies to Paul and Jesse's combined loans. To determine the amount for which each borrower will be responsible, prorate the amount calculated under Step 4 by each spouse's share of the combined Direct Loan debt. Paul has a Direct Loan debt of $10,000 and Jesse has a Direct Loan debt of $15,000. For Paul, the monthly payment amount will be:

- $10,000 ÷ ($10,000 + $15,000) = 40 percent
- 0.40 × $266.90 = $106.76

For Jesse, the monthly payment amount will be:

- $15,000 ÷ ($10,000 + $15,000) = 60 percent
- 0.60 × $266.90 = $160.14

Example 3. Santiago is single with no dependents and has a combined balance of $60,000 in Direct Loans that are eligible for repayment under the ICR plan. Each of Santiago's loans has an interest rate of 6 percent, and Santiago's AGI is $41,828.

Step 1: Determine the total monthly payment amount based on what Santiago would pay over 12 years using standard amortization. To do this, use the formula that precedes Example 1. In this example, the monthly payment amount would be $585.51.

Step 2: Multiply the result of Step 1 by the income percentage factor shown in the income percentage factors table (see Attachment 1 to this notice) that corresponds to Santiago's AGI. In this example, an AGI of $41,828 corresponds to an income percentage factor of 80.33 percent.

- 0.8033 × $585.51 = $470.34

Step 3: Now, determine the monthly payment amount equal to 20 percent of Santiago's discretionary income (discretionary income is AGI minus the HHS Poverty Guideline amount for a borrower's family size and State of residence). To do this, subtract the HHS Poverty Guideline amount for a family of one from Santiago's AGI, multiply the result by 20 percent, and then divide by 12:

- $41,828 − $15,060 = $26,768
- $26,768 × 0.20 = $5,353.60
- $5,353.60 ÷ 12 = $446.13

Step 4: Compare the amount from Step 2 with the amount from Step 3. In this example, Santiago would pay the amount calculated under Step 3 ($446.13), since this is the lesser of the two amounts.

Interpolation. If an AGI is not included on the income percentage factor table, calculate the income percentage factor through linear interpolation. For example, assume that Jocelyn is single with an AGI of $50,000.

Step 1: Find the closest AGI listed that is less than Jocelyn's AGI of $50,000 ($41,828) and the closest AGI listed that is greater than Jocelyn's AGI of $50,000 ($52,536).

Step 2: Subtract the lower amount from the higher amount (for this discussion we will call the result the ''income interval''):

- $52,536 − $41,828 = $10,708

Step 3: Determine the difference between the two income percentage factors that correspond to the AGIs used in Step 2 (for this discussion, we will call the result the ''income percentage factor interval''):

- 88.77 percent − 80.33 percent = 8.44 percent

Step 4: Subtract from Jocelyn's AGI the closest AGI shown on the chart that is less than Jocelyn's AGI of $50,000:

- $50,000 − $41,828 = $8,172

Step 5: Divide the result of Step 4 by the income interval determined in Step 2:

- $8,172 ÷ $10,708 = 76.32 percent

Step 6: Multiply the result of Step 5 by the income percentage factor interval that was calculated in Step 3:

- 8.44 percent × 76.32 percent = 6.44 percent

Step 7: Add the result of Step 6 to the lower of the two income percentage factors used in Step 3 to calculate the income percentage factor interval for an AGI of $50,000:

- 6.44 percent + 80.33 percent = 86.77 percent (rounded to the nearest hundredth)

The result is the income percentage factor that we will use to calculate Jocelyn's monthly repayment amount under the ICR plan.

Attachment 3—Charts Showing Sample Income Contingent Repayment (ICR) Plan Amounts for Single and Married Borrowers

Below are two charts that provide first-year payment amount estimates for a variety of loan debt sizes and AGIs

under the ICR plan. The first chart is for a single borrower who has a family size of one. The second chart is for a borrower who is married or a head of household and who has a family size of three. The calculations in Attachment 3 assume that the loan debt has an interest rate of 6 percent. For the married borrower, the calculations assume that the borrower files a joint Federal income tax return and that the borrower's spouse does not have Federal student loans.

SAMPLE FIRST-YEAR MONTHLY REPAYMENT AMOUNTS FOR A SINGLE BORROWER

Family size = 1					
Initial debt	AGI				
	$20,000	$40,000	$60,000	$80,000	$100,000
$20,000	$82	$152	$186	$196	$222
$40,000	82	305	371	393	445
$60,000	82	416	557	589	667
$80,000	82	416	742	785	889
$100,000	82	416	749	981	1,111

SAMPLE FIRST-YEAR MONTHLY REPAYMENT AMOUNTS FOR A MARRIED OR HEAD-OF-HOUSEHOLD BORROWER

Family size = 3					
Initial debt	AGI				
	$20,000	$40,000	$60,000	$80,000	$100,000
$20,000	$0	$144	$185	$196	$214
$40,000	0	236	369	392	428
$60,000	0	236	554	588	643
$80,000	0	236	570	783	857
$100,000	0	236	570	903	1,071

[FR Doc. 2024–07263 Filed 4–4–24; 8:45 am]
BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board Chairs

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB) Chairs. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, May 1, 2024; 8 a.m.–5 p.m. EDT. Thursday. May 2, 2024; 8 a.m.–12:15 p.m. EDT.

ADDRESSES: Christopher Conference Center, 20 North Plaza Boulevard, Chillicothe, OH 45601.

FOR FURTHER INFORMATION CONTACT: Kelly Snyder, EM SSAB Designated Federal Officer, 702–918–6715 or by email at *kelly.snyder@em.doe.gov* or visit *https://energy.gov/em/listings/chairs-meetings.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to the Department of Energy Environmental Management Program in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda Topics

Wednesday, May 1, 2024

- Program Updates
- Chairs Round Robin
- Public Comment
- Board Business/Open Discussion

Thursday, May 2, 2024

- Public Comment
- Board Business/Open Discussion

Public Participation: This meeting will be open to the public and public comments will be accepted. Public comments can be submitted from those unable to attend. Comments received in writing no later than 5:00 p.m. EDT on Monday, April 29, 2024, will be read aloud during the meeting. Please send comments to Kelly Snyder at *kelly.snyder@em.doe.gov.* The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business.

Minutes: Minutes will also be available at the following website: *https://energy.gov/em/listings/chairs-meetings.*

Signing Authority: This document of the Department of Energy was signed on March 29, 2024, by David Borak, Deputy Committee Management Officer, 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 April 2, 2024.

Treena V. Garrett,

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

[FR Doc. 2024–07247 Filed 4–4–24; 8:45 am]
BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

Final Allocation of Provo River Project Power

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of the final allocation of Provo River Project power.

SUMMARY: Western Area Power Administration (WAPA) Colorado River Storage Project (CRSP) Management Center (MC), a federal Power Marketing Administration of the Department of Energy (DOE), announces its Final Allocation of Provo River Project Power. WAPA's Final 2025 Provo River Project Marketing Plan and Call for 2025 Resource Pool Applications (Marketing Plan) was published in the **Federal Register** on March 17, 2023. Applications for an allocation of Provo River Project power were due June 15, 2023. WAPA reviewed and considered the single application received and published the 2025 Provo River Project Resource Pool Proposed Power Allocation in the **Federal Register** on October 31, 2023. The 60-day comment period for the proposed allocations closed on January 2, 2024. WAPA received and considered two formal comments. This **Federal Register** notice establishes the Final Allocation of Provo River Project Power.

DATES: The final allocations will be effective on May 6, 2024.

ADDRESSES: All documentation retained by WAPA for the purpose of developing the final power allocation, including comments, letters, and other supporting documents, is available for public inspection and copying at the CRSP Management Center, Western Area Power Administration, 1800 South Rio Grande Avenue, Montrose, CO 81401. Public comments and related information may be accessed from the CRSP website at: *www.wapa.gov/about-wapa/regions/crsp/power-marketing/2025-provo-power-marketing-plan/.*

FOR FURTHER INFORMATION CONTACT: Mr. Brent Osiek, Vice President of Power Marketing for CRSP, 801–244–9519 or *Osiek@wapa.gov;* or Mr. Randolph Manion, CRSP Contracts and Energy Services Manager, *Manion@wapa.gov,* 720–201–3285. Written requests for information should be sent to CRSP Management Center, Western Area Power Administration, 1800 South Rio Grande Avenue, Montrose, CO 81401; faxed to 970–240–6282; or emailed to: *Provo-Marketing@wapa.gov.*

SUPPLEMENTARY INFORMATION: WAPA is responsible for marketing power from the Provo River Project, which is done independently from the other projects marketed by WAPA's CRSP MC, including the Salt Lake City Area Integrated Projects (SLCA/IP), Olmsted Project, and the Falcon-Amistad Projects. In addition to marketing power from these federal hydroelectric projects, WAPA's CRSP MC is responsible for approximately 2,316 miles of transmission lines and associated infrastructure across Arizona, New Mexico, Colorado, Utah, and Wyoming.

The Provo River Project is a small water development project, with a powerplant located in northern Utah. It was authorized by President Franklin D. Roosevelt, in part, as a response to the Great Depression and a severe drought that devastated Utah's agriculture and threatened municipal water supplies in the 1930s. The Provo River Project's primary function is to provide irrigation, municipal, and industrial water to users in Salt Lake and Utah Counties, Utah. The Department of the Interior, Bureau of Reclamation (Reclamation), finished construction of the Deer Creek Dam in 1938 and the Deer Creek Powerplant in 1958, which included two 2.475-megawatt generators. On June 27, 1936, Reclamation signed contract number Ilr–874 making the Provo River Water Users' Association (PRWUA) the operator of the dam and responsible for repayment of the Provo River Project. The initial investment in the power facilities was repaid in 1984 but there are ongoing costs associated with operation, maintenance, and replacement of equipment. Surplus power revenues may be used to aid the repayment of the Provo River Project irrigation investment.

Between October 15 and April 15, water may be diverted from the adjacent Weber River Basin into the Provo River Basin and stored in Deer Creek Reservoir for irrigation, municipal, and industrial purposes pursuant to the terms of the 1938 contract number Ilr–1082 between the PRWUA, PacifiCorp (formerly Utah Power and Light Company), and Reclamation, among others. The diversion creates a loss of power generation at the Weber Powerplant on the Weber River, downstream from the diversion. As a result, PacifiCorp, the owner of the Weber Powerplant, is reimbursed for its winter energy losses with Provo River Project power (Weber/Provo Water Exchange). During this winter period, Provo River Project generation above the power reimbursement amount owed to PacifiCorp is sold to Provo River Project customers as non-firm surplus energy; during the summer period, Provo River Project generation is sold to customers as non-firm energy, both without capacity. It is expected that the annual energy production from the Provo River Project will average around 17,243,527 kilowatt-hours per year.

Response to Comments on the Provo River Project 2025 Resource Pool Proposed Power Allocation

WAPA's Final 2025 Provo River Project Marketing Plan and Call for 2025 Resource Pool Applications (Marketing Plan) was published in the **Federal Register** on March 17, 2023 (88 FR 16433). WAPA reviewed and considered the single application received and published the 2025 Provo River Project Resource Pool Proposed Power Allocation and initiated a public comment period in the **Federal Register** on October 31, 2023 (88 FR 74488). During the public comment period, WAPA received one written comment and one verbal comment on the proposal. In preparing the Final Allocation of Provo River Project Power, WAPA reviewed and considered both comments received. This section summarizes and responds to those comments.

Comment(s): Utah Associated Municipal Power Systems (UAMPS) submitted one oral and one written comment, both in support of WAPA's proposal not to alter existing power allocations under the 2025 Resource Pool. UAMPS submitted an application for a portion of the 2025 Resource Pool on behalf of three of its members currently receiving Provo River Project power (Payson, Utah; Springville City, Utah; and South Utah Valley Electric Service District) to pursue a share of the 2025 Resource Pool in the event of reallocation to new applicants. However, UAMPS stated its preference was to not reallocate power under the Resource Pool.

Response: WAPA appreciates UAMPS comments in support of the proposal.

Resource Pool Power Allocation

WAPA did not receive applications for Provo River Project power from new, eligible preference entities. As noted, UAMPS submitted an application on behalf of three of its members, all existing Provo River Project contractors. After analyzing the application and taking into consideration all existing federal hydropower allocations to all Provo River Project contractors, WAPA determined no significant benefit of additional widespread use would occur by continuing forward with the 2025 Resource Pool. Therefore, WAPA will not reduce Provo River Project contractor allocations by 3 percent and will not reallocate power under the 2025 Resource Pool. All current Provo River Project allocations will remain unchanged, as defined in the Final Allocation of Provo River Project Power table below:

Allotee	Percentage entitlement	On behalf of, if applicable	Sub-percentage entitlement, if applicable
Heber Light and Power	6.0	Not applicable.	
UAMPS (In Total)	24.0		
		Lehi	2.7
		Springville	12.9
		Payson	4.8
		South Utah Valley ESD	3.6
Utah Municipal Power Agency (In Total)	70.0		
		Provo	60.9
		Salem	1.4
		Spanish Fork	7.7

Contracting Process

After the effective date of this notice, WAPA will begin the contracting process pursuant to the Marketing Plan. That process requires each individual allottee identified in the table above to execute and return without modification WAPA's electric service contract to purchase Provo River Project energy within 6 months of the contract offer, unless otherwise agreed to in writing by WAPA. WAPA reserves the right to withdraw and reallocate any allocation if an allottee does not execute the new electric service contract by close of business September 30, 2024. The date of initial service under these contracts will be October 1, 2024, and these contracts will remain in effect through September 30, 2054.

If there is any unallocated power after this process, WAPA reserves the right to reallocate such power according to the eligibility and allocation criteria set forth in the Marketing Plan. Entities who have submitted an application pursuant to this process need not re-submit an application if they wish to be considered. WAPA will contact such eligible entities.

Legal Authority

The Marketing Plan, published in the **Federal Register** (88 FR 16433) on March 17, 2023, was established under the following authorities: the Provo River Project was initially authorized under a feasibility finding of the Secretary of the Interior, which was approved by the President, on November 16, 1935, pursuant to § 4 of the Act of June 25, 1910 (36 Stat. 836), and subsection B of § 4 of the Act of December 5, 1924 (43 Stat. 702) (see also Act of March 29, 1948, ch. 159, 62 Stat. 92); Reclamation Act of June 17, 1902 (Pub. L. 57–161) (32 Stat. 388); Reclamation Project Act of August 4, 1939 (Pub. L. 76–260) (53 Stat. 1187); Department of Energy Organization Act of August 4, 1977 (Pub. L. 95–91) (91 Stat. 565); and Reclamation Projects Authorization and Adjustment Act of 1992 (Pub. L. 102–575) (106 Stat. 4600, 4605), as such acts may be supplemented or amended. Allocating power from the resource pool falls within the Marketing Plan and is covered by this authority.

Regulatory Procedure Requirements

A. Review Under the National Environmental Policy Act (NEPA)

WAPA has determined that this proposed action fits within the categorical exclusion listed in Appendix B to subpart D of 10 CFR part 1021 (B4.1 contracts, policies, and marketing and allocation plans for electric power). Categorically excluded projects and activities do not require preparation of either an environmental impact statement or an environmental assessment. A copy of the categorical exclusion determination is available on the CRSP website at: *wapa.gov/wp-content/uploads/2023/04/cx-02-14-22-prp-marketing-plan.pdf.*

B. Determination Under Executive Order 12866

WAPA has an exemption from centralized regulatory review under Executive Order 12866. Accordingly, no clearance of this notice by the Office of Management and Budget is required.

Signing Authority

This document of the Department of Energy was signed on April 1, 2024, by Tracey A. LeBeau, Administrator, Western Area Power Administration pursuant to the above identified legal authority. 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 this 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 April 2, 2024.

Treena V. Garrett,

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

[FR Doc. 2024–07293 Filed 4–4–24; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

Central Arizona Project, Colorado River Storage Project, Loveland Area Projects, Pacific Northwest-Pacific Southwest Intertie Project, and Parker-Davis Project—Rate Order No. WAPA–215

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of rate order extending the formula rates for use under the WestConnect Point-to-Point Regional Transmission Service Participation Agreement (WestConnect PA).

SUMMARY: The extension of the Colorado River Storage Project Management Center (CRSP MC), Desert Southwest Region (DSW), and Rocky Mountain Region's (RM) (collectively referred to herein as the ''Regions'') existing transmission service formula rates for use under the WestConnect PA has been confirmed, approved, and placed into effect on an interim basis. The existing formula rates under Rate Schedule WC–8 are set to expire on May 31, 2024. This rate extension makes no changes to the existing formula rates and extends them through September 30, 2026.

DATES: The extended formula rates under Rate Schedule WC–8 will be placed into effect on an interim basis on June 1, 2024.

FOR FURTHER INFORMATION CONTACT: Rodney Bailey, Manager, CRSP MC, Western Area Power Administration, 1800 South Rio Grande Avenue, Montrose, CO 81401, or email: *CRSPMC-rate-adj@wapa.gov;* Tamala

Gheller, Rates Manager, CRSP MC, 970–240–6545, or email: *gheller@wapa.gov;* Tina Ramsey, Rates Manager, DSW, 602–605–2525, or email: *dswpwrmrk@wapa.gov;* or Sheila Cook, Rates Manager, RM, 970–685–9562, or email: *laptransadj@wapa.gov.*

SUPPLEMENTARY INFORMATION: Western Area Power Administration (WAPA) published a **Federal Register** notice (Proposed FRN) on January 19, 2024 (89 FR 3651), proposing to extend the existing formula rates under Rate Schedule WC–8. The Proposed FRN initiated a 14-day public consultation and comment period.

Legal Authority

By Delegation Order No. S1–DEL–RATES–2016, effective November 19, 2016, the Secretary of Energy delegated: (1) the authority to develop power and transmission rates to the WAPA Administrator; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, or to remand or disapprove such rates, to the Federal Energy Regulatory Commission (FERC). By Delegation Order No. S1–DEL–S3–2023, effective April 10, 2023, the Secretary of Energy also delegated the authority to confirm, approve, and place such rates into effect on an interim basis to the Under Secretary for Infrastructure. By Redelegation Order No. S3–DEL–WAPA1–2023, effective April 10, 2023, the Under Secretary for Infrastructure further redelegated the authority to confirm, approve, and place such rates into effect on an interim basis to WAPA's Administrator. This extension is issued under Redelegation Order No. S3–DEL–WAPA1–2023 and Department of Energy rate extension procedures set forth in 10 CFR part 903.[1]

Following review of the Regions' proposal, Rate Order No. WAPA–215 is hereby confirmed, approved, and placed into effect on an interim basis. This extends, without adjustment, the existing Rate Schedule WC–8 through September 30, 2026. WAPA will submit Rate Order No. WAPA–215 and the extended rate schedule to FERC for confirmation and approval on a final basis.

Department of Energy Administrator, Western Area Power Administration

In the Matter of: Western Area Power Administration, Extension for the Central Arizona Project, Colorado River Storage Project, Loveland Area Projects, Pacific Northwest-Pacific Southwest Intertie Project, Parker-Davis Project Transmission Service Formula Rates, Rate Order No. WAPA–215

Order Confirming, Approving, and Placing the Formula Rates for Central Arizona Project, Colorado River Storage Project, Loveland Area Projects, Pacific Northwest-Pacific Southwest Intertie Project, and Parker-Davis Project Transmission Service for Use Under the Westconnect Point-to-Point Regional Transmission Service Participation Agreement Into Effect on an Interim Basis

The formula rates in Rate Order No. WAPA–215 are established following Section 302 of the Department of Energy (DOE) Organization Act (42 U.S.C. 7152).[1] By Delegation Order No. S1–DEL–RATES–2016, effective November 19, 2016, the Secretary of Energy delegated: (1) the authority to develop power and transmission rates to the Western Area Power Administration (WAPA) Administrator; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, or to remand or disapprove such rates, to the Federal Energy Regulatory Commission (FERC). By Delegation Order No. S1–DEL–S3–2023, effective April 10, 2023, the Secretary of Energy also delegated the authority to confirm, approve, and place such rates into effect on an interim basis to the Under Secretary for Infrastructure. By Redelegation Order No. S3–DEL–WAPA1–2023, effective April 10, 2023, the Under Secretary for Infrastructure further redelegated the authority to confirm, approve, and place such rates into effect on an interim basis to WAPA's Administrator. This extension is issued under Redelegation Order No. S3–DEL–WAPA1–2023 and DOE rate extension procedures set forth in 10 CFR part 903.[2]

Background

On December 15, 2014, FERC approved and confirmed Rate Schedule WC–8, under Rate Order No. WAPA–163, on a final basis for a 5-year period through May 31, 2019.[3] On June 20, 2019, FERC approved and confirmed the extension of Rate Schedule WC–8, under Rate Order No. WAPA–187, on a final basis through May 31, 2024.[4] This rate schedule applies to WestConnect regional on-peak and off-peak non-firm transmission service that uses one or more of the following WAPA transmission projects: Central Arizona Project, Colorado River Storage Project, Loveland Area Projects, Pacific Northwest-Pacific Southwest Intertie Project, and Parker-Davis Project. Details about the rate schedule and the formula rates are viewable on WAPA's website at: *www.wapa.gov/about-wapa/regions/dsw/power-marketing/westconnect.* The rate continues the formula-based methodology that includes an annual update to the data in the rate formulas which provides adequate revenue to recover annual expenses, including interest expense, and repay capital investment within the allowable periods. This ensures repayment within the cost recovery criteria set forth in DOE Order RA 6120.2.

Discussion

In accordance with 10 CFR 903.23(a), the Colorado River Storage Project Management Center (CRSP MC), Desert Southwest Region (DSW), and Rocky Mountain Region (RM) (collectively referred to herein as the ''Regions'') published a notice in the **Federal Register** (Proposed FRN) on January 19, 2024, proposing to extend, without adjustment, Rate Schedule WC–8 under Rate Order No. WAPA–215.[5] The Regions determined it was not necessary to hold public information or public comment forums on the proposed formula rate extension, but provided a 14-day consultation and comment period to give the public an opportunity to comment on the proposed extension. During the 14-day consultation and comment period, which ended on February 2, 2024, the Regions received written comments from one entity.

Written comments were received from the following organization: Colorado River Energy Distributors Association, Arizona.

Comments

The comments expressed have been paraphrased and/or combined, where

[1] 50 FR 37835 (Sept. 18, 1985) and 84 FR 5347 (Feb. 21, 2019).

[1] This Act transferred to, and vested in, the Secretary of Energy the power marketing functions of the Secretary of the Department of the Interior and the Bureau of Reclamation (Reclamation) under the Reclamation Act of 1902 (ch. 1093, 32 Stat. 388), as amended and supplemented by subsequent laws, particularly section 9(c) of the Reclamation Project Act of 1939 (43 U.S.C. 485h(c)); and other acts that specifically apply to the projects involved.

[2] 50 FR 37835 (Sept. 18, 1985) and 84 FR 5347 (Feb. 21, 2019).

[3] *Order Confirming and Approving Rate Schedule on a Final Basis,* FERC Docket No. EF14–8–000, 149 FERC ¶ 62,196 (2014).

[4] *Order Confirming and Approving Rate Schedule on a Final Basis,* FERC Docket No. EF14–8–001, 167 FERC ¶ 62,188 (2019).

[5] 89 FR 3651 (2024).

appropriate, without compromising the meaning of the comments.

Comment: The commenter supports the proposed formula rate extension as described in the Proposed FRN. The commenter also requested removal of language referenced in the Proposed FRN which was ''unnecessary and refers to potential future actions that are the subject of separate processes.''

Response: The Regions appreciate the support for this rate action. The Regions agree the Proposed FRN language refers to specific future events subject to separate processes and a more general reference to future market activity could have been used. The intent of including the language in the Proposed FRN was to provide context for pursuing an extension as opposed to a major rate action, along with the reasoning for the length of the extension period.

Ratemaking Procedure Requirements

Environmental Compliance

Categorical exclusion determinations were previously issued for the underlying rates of the transmission projects included in the WestConnect PA under the following categorical exclusion listed in appendix B to subpart D of 10 CFR part 1021: B4.3 (Electric power marketing rate changes).[6] Those categorical exclusion determinations are also applicable to this rate action. Copies of the categorical exclusion determinations are available on WAPA websites. For CRSP MC, the website is: *www.wapa.gov/about-wapa/regions/crsp/about-crsp/environment* and the file is titled ''SLCA/IP Rate Determination—WAPA–206—(CX Determination 2024–2028).'' For DSW, the website is: *www.wapa.gov/about-wapa/regions/dsw/environment.* The file titled, ''Rate Order WAPA–209'' is located within the ''2023'' folder. For RM, the website is: *www.wapa.gov/about-wapa/regions/rm/rm-environment/cx2016* and the file is titled ''2016–077-Proposed-Formula-Rate-Adjustment-for-Transmission-Ancillary-Services-and-Sale-of-Surplus.''

Determination Under Executive Order 12866

WAPA has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this notice by the Office of Management and Budget is required.

[6] These determinations were made in compliance with the National Environmental Policy Act (NEPA) of 1969, as amended, 42 U.S.C. 4321–4347, the Council on Environmental Quality Regulations for implementing NEPA (40 CFR parts 1500–1508); and DOE NEPA Implementing Procedures and Guidelines (10 CFR part 1021).

Submission to the Federal Energy Regulatory Commission

The provisional formula rates herein confirmed, approved, and placed into effect on an interim basis, together with supporting documents, will be submitted to FERC for confirmation and final approval.

Order

In view of the above and under the authority delegated to me, I hereby confirm, approve, and place into effect, on an interim basis, Rate Order No. WAPA–215, which extends the existing formula rates under Rate Schedule WC–8 through September 30, 2026. The rates will remain in effect on an interim basis until: (1) FERC confirms and approves of this extension on a final basis; (2) subsequent rates are confirmed and approved; or (3) such rates are superseded.

Signing Authority

This document of the Department of Energy was signed on April 1, 2024, by Tracey A. LeBeau, Administrator, Western Area Power Administration, pursuant to delegated authority from the Secretary of Energy. That document, with the original signature and date, is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy.

This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on April 2, 2024.

Treena V. Garrett,

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

Rate Schedule WC–8

Schedule 8 to Tariff

United States Department of Energy
Western Area Power Administration

Loveland Area Projects

Colorado River Storage Project

Pacific Northwest-Pacific Southwest Intertie Project

Central Arizona Project

Parker-Davis Project

Schedule of Rates for Use Under Westconnect Regional Non–Firm Transmission Service (Approved Under Rate Order No. WAPA–163)

Effective: The first day of the first full billing period beginning on or after June 1, 2014, through May 31, 2019, unless WAPA withdraws from the WestConnect Point-to-Point Regional Transmission Service Participation Agreement, and posts notice of such withdrawal on the Open Access Same-Time Information System (OASIS), prior to May 31, 2019. [Note: This rate schedule was extended by Rate Order No. WAPA–187 through May 31, 2024, and by Rate Order No. WAPA–215 through September 30, 2026.]

Applicable: This schedule of rates applies to any WestConnect Regional, Non-Firm, Point-to-Point Transmission Service that uses a Western Area Power Administration Transmission Project (TP), *i.e.,* Central Arizona Project, Colorado River Storage Project, Loveland Area Projects, Pacific Northwest-Pacific Southwest Intertie Project, and Parker-Davis Project.

Rate: The transmission rates to be used in this formula rate calculation will be the applicable TP's in effect hourly, non-firm, point-to-point transmission rate as posted on the applicable TP's website and on the OASIS.

Formula Rate Calculation: On-peak, hourly, non-firm, point-to-point transmission rate:

TP's non-firm, point-to-point, ''all hours'' transmission rate 47.49 percent (the percentage of FERC-defined on-peak hours).

Off-peak, hourly, non-firm, point-to-point transmission rate:

TP's non-firm, point-to-point, ''all hours'' transmission rate 52.51 percent (the percentage of FERC-defined off-peak hours).

The converted rates resulting from using this formula will be posted on the applicable TP's website and on the OASIS and will be used for applicable WestConnect Regional Non-Firm Point-to-Point Transmission Service transactions only.

[FR Doc. 2024–07280 Filed 4–4–24; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–11834–01–OA]

Public Meetings of the Science Advisory Board Radionuclide Cancer Risk Coefficients Review Panel

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office is announcing two public meetings of the Science Advisory Board Radionuclide Cancer Risk Coefficients Review Panel. The purpose of the meetings is to receive a briefing from EPA, review and discuss charge questions, listen to public comments and peer review the EPA's draft Cancer Risk Coefficients for Environmental Exposure to Radionuclides (Federal Guidance Report No. 16).

DATES: *Public meeting[s]:* The Science Advisory Board Radionuclide Cancer Risk Coefficients Review Panel will meet on the following dates.

1. April 25, 2024, from 1 p.m. to 5 p.m.
2. May 29, 2024, from 9 a.m. to 5 p.m.
3. May 30, 2024, from 9 a.m. to 5 p.m.
4. May 31, 2024, from 9 a.m. to 3 p.m.

Comments: See the section titled ''Procedures for providing public input'' under **SUPPLEMENTARY INFORMATION** for instructions and deadlines.

ADDRESSES: The April 25, 2024, meeting will be conducted virtually. Please refer to the SAB website at *https://sab.epa.gov* for information on how to attend the meeting. The May 29–31, 2024 meetings will be conducted in person and virtually. Please refer to the SAB website at *https://sab.epa.gov* for information on how to attend the meeting.

FOR FURTHER INFORMATION CONTACT: Any member of the public who wants further information concerning this document may contact Dr. Diana Wong, Designated Federal Officer (DFO), via telephone at (202) 564–2049, or email at *wong.diana-m@epa.gov.* General information about the SAB, as well as any updates concerning the meetings announced in this document, can be found on the SAB website at *https://sab.epa.gov.*

SUPPLEMENTARY INFORMATION:

Background: The SAB was established pursuant to the Environmental Research, Development, and Demonstration Authorization Act (ERDDAA), codified at 42 U.S.C. 4365, to provide independent scientific and technical advice to the EPA Administrator on the scientific and technical basis for agency positions and regulations. The SAB is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C. 10. The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies. Pursuant to FACA and EPA policy, notice is hereby given that the Science Advisory Board Radionuclide Cancer Risk Coefficients Review Panel will hold two public meetings to review and discuss charge questions, listen to agency presentations, listen to public comments and peer review the EPA's draft Cancer Risk Coefficients for Environmental Exposure to Radionuclides (Federal Guidance Report No. 16).

Availability of meeting materials: All meeting materials, including the agenda, will be available on the SAB web page at *https://sab.epa.gov.*

Procedures for providing public input: Public comment for consideration by EPA's Federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a Federal advisory committee is different from the process used to submit comments to an EPA program office. Federal advisory committees and panels, including scientific advisory committees, provide independent advice to the EPA. Members of the public can submit relevant comments pertaining to the committee's charge or meeting materials. Input from the public to the SAB will have the most impact if it provides specific scientific or technical information or analysis for the SAB to consider or if it relates to the clarity or accuracy of the technical information. Members of the public wishing to provide comments should follow the instruction below to submit comments.

Oral statements: In general, individuals or groups requesting an oral presentation at a meeting conducted virtually will be limited to three minutes, and individuals or groups requesting an oral presentation at an in-person meeting will be limited to five minutes. Each person making an oral statement should consider providing written comments as well as their oral statement so that the points presented orally can be expanded upon in writing. Persons interested in providing oral statements should contact the DFO, in writing (preferably via email) at the contact information noted under **FOR FURTHER INFORMATION CONTACT**, by April 18, 2024, for the April 25, 2024 meeting and by May 22, 2024, for the May 29–31, 2024 meeting, to be placed on the list of registered speakers.

Written statements: Written statements will be accepted throughout the advisory process; however, for timely consideration by SAB members, statements should be submitted to the DFO by April 18, 2024, for consideration at the April 25, 2024 meeting and May 22, 2024, for consideration at the May 29–31, 2024 meeting. Written statements should be supplied to the DFO at the contact information above via email. Submitters are requested to provide an unsigned version of each document because the SAB Staff Office does not publish documents with signatures on its websites. Members of the public should be aware that their personal contact information if included in any written comments, may be posted to the SAB website. Copyrighted material will not be posted without the explicit permission of the copyright holder.

Accessibility: For information on access or services for individuals with disabilities, please contact the DFO, at the contact information noted above, preferably at least ten days before the meetings, to give the EPA as much time as possible to process your request.

V Khanna Johnston,

Deputy Director, Science Advisory Board Staff Office.

[FR Doc. 2024–07253 Filed 4–4–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OGC–2024–0166; FRL–11871–01–OGC]

Proposed Consent Decree, Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed consent decree; request for public comment.

SUMMARY: In accordance with the Clean Air Act, as amended (''CAA'' or ''the Act''), the Environmental Protection Agency (''EPA'' or ''the Agency'') is providing notice of a proposed consent decree in *Sierra Club* v. *Michael S. Regan,* No. 1:23–cv–00424–RCL (D.D.C.). On February 15, 2023, Plaintiff Sierra Club filed a complaint in the United States District Court for the District of Columbia alleging that EPA's failure to issue final Federal plans implementing emissions guidelines for commercial and industrial solid waste incinerators (''CISWI''), and other solid waste incinerators (''OSWI'') in states

which had not submitted approvable state plans constituted agency action unreasonably delayed.

DATES: Written comments on the proposed consent decree must be received by May 6, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2024–0166, online at *https://www.regulations.gov* (EPA's preferred method). Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID number for this action. Comments received may be posted without change to *https://www.regulations.gov,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Additional Information about Commenting on the Proposed Consent Decree'' heading under the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Grace Weatherall, Air and Radiation Law Office, Office of General Counsel, U.S. Environmental Protection Agency; telephone: (202) 564–1067; email address: *Weatherall.Grace@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining a Copy of the Proposed Consent Decree

The official public docket for this action (identified by Docket ID No. EPA–HQ–OGC–2024–0166) contains a copy of the proposed consent decree. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1752.

The electronic version of the public docket for this action contains a copy of the proposed consent decree, and is available through *https://www.regulations.gov.* You may use *https://www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select ''search.''

II. Additional Information About the Proposed Consent Decree

Plaintiffs filed a complaint in the United States District Court for the District of Columbia alleging that the EPA's failure to issue final Federal plans implementing emissions guidelines for CISWI and OSWI facilities in states which had not submitted approvable state plans constituted ''agency action unreasonably delayed'' within the meaning of section 304(a)(2) of the Clean Air Act, 42 U.S.C. 7604(a).

EPA promulgated revised CISWI emission guidelines for existing facilities at 40 CFR subpart DDDD in 2011 and further revised them in February 2013, June 2016, and April 2019. EPA proposed a Federal plan for existing CISWI facilities in 2017, and to date, EPA has not promulgated a final Federal plan implementing CISWI standards under 42 U.S.C. 7429(b)(3).

EPA promulgated emission guidelines for existing OSWI facilities in December 2005 at 40 CFR subpart FFFF. To date, EPA has not finalized a Federal plan implementing standards for existing OSWI facilities under 42 U.S.C. 7429(b)(3).

Under the terms of the consent decree, with respect to the CISWI emission guidelines at 40 CFR subpart DDDD, no later than September 16, 2024, the appropriate EPA official would be required to sign a final rule establishing a Federal plan under 42 U.S.C. 7429(b)(3) for existing CISWI facilities located in any state which has not submitted an approvable state plan.

Under the terms of the consent decree, with respect to the OSWI emission guidelines at 40 CFR subpart FFFF, (1) no later than June 30, 2026, the appropriate EPA official would be required to sign a proposed rulemaking proposing a Federal plan under 42 U.S.C. 7429(b)(3) for existing OSWI facilities located in any state which has not submitted an approvable state plan; and (2) no later than June 30, 2027, the appropriate EPA official would be required to sign a final rule establishing a Federal plan under 42 U.S.C. 7429(b)(3) for existing OSWI facilities located in any state which has not submitted an approvable state plan.

In accordance with section 113(g) of the CAA, for a period of thirty (30) days following the date of publication of this notice, the Agency will accept written comments relating to the proposed consent decree. EPA or the Department of Justice may withdraw or withhold consent to the proposed consent decree if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act.

III. Additional Information About Commenting on the Proposed Consent Decree

Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2024–0166, via *https://www.regulations.gov.* Once submitted, comments cannot be edited or removed from this docket. The 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) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* For additional information about submitting information identified as CBI, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document. Note that written comments containing CBI and submitted by mail may be delayed and deliveries or couriers will be received by scheduled appointment only.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the *https://www.regulations.gov* website to submit comments to EPA electronically is

EPA's preferred method for receiving comments. The electronic public docket system is an ''anonymous access'' system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment.

Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

Gautam Srinivasan,

Associate General Counsel.

[FR Doc. 2024–07256 Filed 4–4–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL OP–OFA–120]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed March 25, 2024 10 a.m. EST

Through April 1, 2024 10 a.m. EST

Pursuant to 40 CFR 1506.9.

Notice: Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxapps.epa.gov/cdx-enepa-II/public/action/eis/search.*

EIS No. 20240057, Final, NMFS, NY, ADOPTION—Sunrise Wind Project, Contact: Jaclyn Daly 301–427–8401.

The National Marine Fisheries Service (NMFS) has adopted the Bureau of Ocean Energy Management's Final EIS No. 20230178 filed 12/11/2023 with the Environmental Protection Agency. The NMFS was a cooperating agency on this project. Therefore, republication of the document is not necessary under Section 1506.3(b)(2) of the CEQ regulations.

EIS No. 20240058, Draft, FERC, ME, Weston, Lockwood, and Hydro Kennebec Projects, and the relicensing of the Shawmut Project, Comment Period Ends: 06/04/2024, Contact: Office of External Affairs 866–208–3372.

EIS No. 20240059, Final, GSA, AZ, Expansion and Modernization of the Raul Hector Castro Land Port of Entry and Proposed Commercial Land Port of Entry in Douglas, Arizona, Review Period Ends: 05/06/2024, Contact: Osmahn Kadri 415–522–3617.

EIS No. 20240060, Final Supplement, NRC, FL, Site-Specific Environmental Impact Statement for License Renewal of Nuclear Plants Regarding Subsequent License Renewal for Turkey Point Nuclear Generating Unit Nos. 3 and 4, NUREG–1437, Supplement 5a, Second Renewal, Final Report (NUREG–1437), Review Period Ends: 05/06/2024, Contact: Lance Rakovan 301–415–2589.

EIS No. 20240061, Draft, BLM, NM, Organ Mountains-Desert Peaks National Monument Draft Resource Management Plan and Environmental Impact Statement, Comment Period Ends: 07/05/2024, Contact: Patrick Rich, RMP Team Lead 405–579–7154.

EIS No. 20240062, Draft, BLM, OR, Draft Resource Management Plan and Environmental Impact Statement Cascade-Siskiyou National Monument, Comment Period Ends: 07/05/2024, Contact: Nikki Haskett 202–740–0835.

Dated: April 1, 2024.

Julie A. Roemele,

Acting Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2024–07250 Filed 4–4–24; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

TIME AND DATE: Tuesday, April 16, 2024 at 10 a.m. and its continuation at the conclusion of the open meeting on April 18, 2024.

PLACE: 1050 First Street NE, Washington, DC, and virtual. (This meeting will be a hybrid meeting.)

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Compliance matters pursuant to 52 U.S.C. 30109.

Matters relating to internal personnel decisions, or internal rules and practices.

Information the premature disclosure of which would be likely to have a considerable adverse effect on the implementation of a proposed Commission action.

Matters concerning participation in civil actions or proceedings or arbitration.

* * * * *

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer. Telephone: (202) 694–1220.

(Authority: Government in the Sunshine Act, 5 U.S.C. 552b)

Vicktoria J. Allen,

Deputy Secretary of the Commission.

[FR Doc. 2024–07389 Filed 4–3–24; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Savings and Loan Holding Company

The notificants listed below have applied under the Change in Bank Control Act (''Act'') (12 U.S.C. 1817(j)) and of the Board's Regulation LL (12 CFR 238.31) to acquire shares of a savings and loan holding company. The factors that are considered in acting on the notices are set forth in paragraph 6 of the Act (12 U.S.C. 1817(j)(6)).

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 6 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, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than April 22, 2024.

A. Federal Reserve Bank of St. Louis (Holly A. Rieser, Senior Manager) P.O. Box 442, St. Louis, Missouri 63166–2034. Comments can also be sent electronically to *Comments.applications@stls.frb.org:*

1. *The Murray Bank 401(K) Employee Ownership Plan, along with Robert Wayne Hargrove, James Suart Poston,*

Charles Stephen Story, individually and as co-trustees, all of Murray, Kentucky; to retain voting shares of BancKentucky, Inc., and thereby indirectly retain voting shares of The Murray Bank, both of Murray, Kentucky.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024–07297 Filed 4–4–24; 8:45 am]

BILLING CODE 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, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than April 22, 2024.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, IL 60604. Comments can also be sent electronically to *Comments.applications@chi.frb.org:*

1. *Foote Shingleton 2004 Irrevocable Trust fbo Elizabeth Shingleton Glomsrud, Foote Shingleton 2004 Irrevocable Trust fbo Jennifer Shingleton Ewing, and Foote Shingleton 2004 Irrevocable Trust, fbo Rebecca Shingleton, all of Sanibel, Florida, and Kenneth Foote, Brighton, Michigan, as trustee of each of these trusts; Mamie M. Foote Trust No. 1, Mamie M. Foote, as trustee, both of Golden Oak, Florida; The William R. Thomas Trust dated 8/26/20, William Thomas and Megan Furman as trustees, all of Ann Arbor, Michigan; and Abigail Thomas King, Charlotte, North Carolina,* to join the Foote Family Control Group, a group acting in concert, and to acquire voting shares of First National Bancshares, Inc., and thereby indirectly control First National Bank of America, both of East Lansing, Michigan.

B. 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. *Karen C. Smith, Ada, Oklahoma;* to join the Smith Family Group, a group acting in concert, to retain voting shares of CitizensAda Financial Corporation, and thereby indirectly retain voting shares of Citizens Bank of Ada, both of Ada, Oklahoma.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024–07298 Filed 4–4–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0076; Docket No. 2024–0053; Sequence No. 8]

Information Collection; Novation and Change-of-Name Agreements

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, and the Office of Management and Budget (OMB) regulations, DoD, GSA, and NASA invite the public to comment on an extension concerning novation and change-of-name agreements. 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 July 31, 2024. DoD, GSA, and NASA propose that OMB extend its approval for use for three additional years beyond the current expiration date.

DATES: DoD, GSA, and NASA will consider all comments received by June 4, 2024.

ADDRESSES: 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. 9000–0076, Novation and Change-of-Name Agreements. 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: Zenaida Delgado, Procurement Analyst, at telephone 202–969–7207, or *zenaida.delgado@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. OMB Control Number, Title, and Any Associated Form(s)

9000–0076, Novation and Change-of-Name Agreements.

B. Need and Uses

This clearance covers the information that contractors must submit to comply with the following requirements in

Federal Acquisition Regulation (FAR) subpart 42.12:

• *FAR 42.1203(a), Written Request.* If a contractor wishes the Government to recognize a successor in interest to its contracts or a name change, the contractor must submit a written request to the responsible contracting officer. The request is used by the contracting officer to determine what additional supporting documentation should be submitted by the contractor and to determine what other contract administration offices should be notified of the contractor's request.

• *FAR 42.1204(e) and (f), Novation Agreement.* Pursuant to FAR 42.1203(b)(1), upon request from the contracting officer, the contractor shall submit three signed copies of the proposed novation agreement, plus copies of the supporting documentation listed at 42.1204(e) and (f), as applicable. The documentation is used by the contracting officer to evaluate and, if appropriate, execute a proposed agreement for recognizing a third party as a successor in interest.

• *FAR 42.1205(a), Change-of-Name Agreement.* Pursuant to FAR 42.1203(b)(1), upon request from the contracting officer, the contractor shall submit three signed copies of the proposed change-of-name agreement, plus copies of the supporting documentation listed at 42.1205(a), as applicable. The documentation is used by the contracting officer to evaluate and, if appropriate, execute a proposed agreement for recognizing a contractor's name change.

C. Annual Burden

Respondents: 1,625.

Total Annual Responses: 1,625.

Total Burden Hours: 3,163.

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. 9000–0076, Novation and Change-of-Name Agreements.

William Clark,

Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2024–07276 Filed 4–4–24; 8:45 am]

BILLING CODE 6820–EP–P

GENERAL SERVICES ADMINISTRATION

[Notice—PBS–2024–05; Docket No. 2024–0002; Sequence No. 13]

Notice of Availability for a Final Environmental Impact Statement and Finding of No Practicable Alternative for the Expansion and Modernization of the Raul Hector Castro Land Port of Entry and Proposed Commercial Land Port of Entry in Douglas, Arizona

AGENCY: Public Buildings Service (PBS), General Services Administration (GSA).

ACTION: Notice of availability, finding of no practicable alternative (FONPA).

SUMMARY: This notice announces the availability of the Final Environmental Impact Statement (FEIS), which examines the potential environmental impacts from the expansion and modernization of the Raul Hector Castro (RHC) Land Port of Entry (LPOE) in Douglas, Arizona and construction of a new Commercial LPOE to address various operational, capacity, and safety issues associated with the existing facility.

DATES:

Wait Period—The FEIS Wait Period begins with publication of this notice in the **Federal Register** and will last for 30 days until May 6th, 2024. Any final written comments must be received by the last day of the Wait Period (see **ADDRESSES** section of this notice on how to submit comments). After the Wait Period, GSA will finalize the ROD.

Meeting Date—A public meeting will be held on Wednesday, April 24, 2024, from 4 p.m. to 6 p.m. mountain time. The meeting will be held in the Douglas Government Center (see **ADDRESSES** section of this notice).

ADDRESSES:

Meeting Location—A public meeting will be held at the Douglas Government Center, 1012 N G Ave., Douglas, AZ 85607.

Public Comments—Any final written comments may be submitted at the public meeting or by one of the following methods.

• *Email: Osmahn.Kadri@gsa.gov.* Please include '*Douglas Commercial and RHC LPOE EIS*' in the subject line of the message.

• *Mail: ATTN: Osmahn Kadri, Douglas Commercial and RHC LPOE EIS;* U.S. General Services Administration, c/o Potomac-Hudson Engineering, Inc., 77 Upper Rock Circle, Suite 302, Rockville, MD 20850.

FOR FURTHER INFORMATION CONTACT: Questions on the FEIS or public meeting should be directed to: Osmahn Kadri, NEPA Program Manager, GSA at 415–522–3617, or via email to *Osmahn.Kadri@gsa.gov.* Please also call the number if special assistance is needed to attend and participate in the public meeting.

SUPPLEMENTARY INFORMATION: The FEIS describes the purpose and need for the project; alternatives considered; the existing environment that could be affected; the potential impacts resulting from each of the alternatives; and proposed best management practices and/or mitigation measures. The FEIS also includes a Floodplain Assessment and Statement of Findings, which provides a FONPA for construction in floodplains at the proposed Commercial LPOE and RHC LPOE. The floodplain assessment was revised to include floodplain impacts at the Commercial LPOE due to updated hydrologic data. Based on impacts analyses and public comments, GSA has identified Alternative 2 (Concurrent Construction—Westward Expansion) as its preferred alternative. GSA has also identified sub-alternative d (combination of adaptive reuse, relocation, or demolition) as the preferred alternative for managing historic structures at the RHC LPOE. GSA is continuing consultation with the State Historic Preservation Office as required under section 106 of the National Historic Preservation Act, and updates will be provided in the Record of Decision (ROD). Under the Endangered Species Act, GSA coordinated with the U.S. Fish and Wildlife Service (USFWS) per section 7 requirements to determine effects to federally protected species. The USFWS concurred with GSA findings that the Proposed Action would not likely adversely affect federally threatened or endangered species. Correspondence with USFWS and the findings are incorporated in the FEIS.

Public Comment Period

The views and comments of the public are necessary in helping GSA in its decision-making process with impacts to environmental, cultural, and economic impacts. The meeting will be an informal open house, where visitors may speak with GSA representatives and provide written comments on the FEIS and FONPA. No formal presentation will be provided. All comments will be considered equally and will be part of the public record.

Additional information on the project, including an electronic copy of the FEIS, may also be found online at: *https://www.gsa.gov/about-us/regions/welcome-to-the-pacific-rim-region-9/*

land-ports-of-entry/douglas-commercial-land-port-of-entry and *https://www.gsa.gov/about-us/regions/welcome-to-the-pacific-rim-region-9/land-ports-of-entry/raul-hector-castro-land-port-of-entry.*

Russell Larson,

Director, Portfolio Management Division, Pacific Rim Region, Public Buildings Service.

[FR Doc. 2024–07032 Filed 4–4–24; 8:45 am]

BILLING CODE 6820–YF–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Meetings

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of five AHRQ subcommittee meetings.

SUMMARY: The subcommittees listed below are part of AHRQ's Health Services Research Initial Review Group (IRG) Committee. Grant applications are to be reviewed and discussed at these meetings. Each subcommittee meeting will be closed to the public.

DATES: See below for dates of meetings:

1. Healthcare Research Training (HCRT)
   Date: May 16–17, 2024
   July 19, 2024
2. Healthcare Safety and Quality Improvement Research (HSQR)
   Date: May 22–23, 2024
3. Healthcare Effectiveness and Outcomes Research (HEOR)
   Date: June 5–6, 2024
4. Healthcare Information Technology Research (HITR)
   Date: June 6–7, 2024
5. Health System and Value Research (HSVR)
   Date: June 13–14, 2024

ADDRESSES: Agency for Healthcare Research and Quality (Virtual Review), 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: (To obtain a roster of members, agenda or minutes of the non-confidential portions of the meetings.)

Jenny Griffith, Committee Management Officer, Division of Policy, Coordination and Analysis, Office of Extramural Research Education and Priority Populations, Agency for Healthcare Research and Quality (AHRQ), 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 427–1557

SUPPLEMENTARY INFORMATION: In accordance with the Federal Advisory Committee Act, 5 U.S.C. 1009(a)(2), AHRQ announces meetings of the above-listed scientific peer review groups, which are subcommittees of AHRQ's Health Services Research Initial Review Group Committee. The subcommittee meetings will be closed to the public in accordance with the provisions set forth in 5 U.S.C. 1009(d), 5 U.S.C. 552b(c)(4), and 5 U.S.C. 552b(c)(6). 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.

Agenda items for these meetings are subject to change as priorities dictate.

Dated: April 2, 2024.

Marquita Cullom,

Associate Director.

[FR Doc. 2024–07295 Filed 4–4–24; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Injury Prevention and Control

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of closed meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC) announces the following meeting for the Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC). This meeting is closed to the public.

DATES: The meeting will be held on May 14, 2024, from 10 a.m. to 1 p.m., EDT (CLOSED).

ADDRESSES: Webinar, Atlanta, Georgia.

FOR FURTHER INFORMATION CONTACT: Christopher R. Harper, Ph.D., Designated Federal Officer, Board of Scientific Counselors, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Highway NE, Mailstop S–1069, Atlanta, Georgia 30341. Telephone: (404) 718–8330; Email: *ncipcbsc@cdc.gov.*

SUPPLEMENTARY INFORMATION: The meeting referenced above will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5, U.S.C., and the Determination of the Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, pursuant to 5 U.S.C. 1009(d) (Pub. L. 92–463, as amended).

Purpose: The Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC) will: (1) conduct, encourage, cooperate with, and assist other appropriate public health authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes and strategies related to the prevention of injury, overdose, and violence; (2) assist States and other entities in preventing intentional and unintentional injuries, and to promote health and well-being; and (3) make recommendations of grants and cooperative agreements for research and prevention activities related to injury, overdose, and violence. The BSC, NCIPC makes recommendations regarding policies, strategies, objectives, and priorities and reviews progress toward injury, overdose, and violence prevention. The Board also provides advice on the appropriate balance of intramural and extramural research and provides guidance on the needs, structure, progress, and performance of intramural programs. Further, the Board provides guidance on extramural scientific program matters. Additionally, the Board provides second-level scientific and programmatic review of applications for research grants, cooperative agreements, and training grants related to injury, overdose, and violence prevention, and recommends approval of projects that merit further consideration for funding support. The Board also provides feedback and input on strategic plans, resources, and priority publications related to injury, overdose, and violence prevention.

Matters to be Considered: The closed meeting will focus on the secondary peer review of extramural research grant applications received in response to three (3) Notices of Funding Opportunity: RFA–CE–24–013—''Research Grants to Identify Effective Community-Based Strategies for Overdose Prevention''; RFA–CE–24–029—''Grants to Support New Investigators in Conducting Research Related to Preventing Interpersonal Violence Impacting Children and Youth''; and RFA–CE–24–034—''Rigorous Evaluation of Policies for their Impacts on the Primary Prevention

of Multiple Forms of Violence.'' Agenda items are subject to change as priorities dictate.

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–07300 Filed 4–4–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–24–24EE; Docket No. CDC–2024–0023]

Proposed Data Collection Submitted for Public Comment and Recommendations

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), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled DFWED National Hypothesis Generation and Investigation Module. The proposed data collection will define a core set of standardized data elements and forms used for outbreak investigations and surveillance activities for a variety of enteric illnesses.

DATES: CDC must receive written comments on or before June 4, 2024.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2024–0023 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

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. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

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;

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; and

5. Assess information collection costs.

Proposed Project

DFWED National Hypothesis Generation and Investigation Module—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) at the Centers for Disease Control and Prevention (CDC) aims to protect public health through the prevention and control of disease, disability, and death caused by foodborne, enteric, waterborne, and environmentally transmitted infections. To overcome challenges presented by the changing landscape of enteric diseases, the need for comprehensive hypothesis generating questionnaires focused on a range of settings, activities, and potential modes of transmission are essential to guide prevention and control activities. The submitted forms standardize hypothesis generating instruments used during enteric disease outbreak investigations and surveillance. This includes foodborne, waterborne, and zoonotic disease surveillance and outbreak investigations. In addition, enhanced surveillance for antibiotic resistant isolates is also included in this package.

CDC requests OMB approval for an estimated 5,852 annual burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Cluster and outbreak case patients	National Hypothesis Generating Questionnaire.	4,000	1	45/60	3,000
Cluster and outbreak case patients	Foodborne Focus Questionnaire.	4,000	1	20/60	1,333
Cluster and outbreak case patients	Animal Contact Focus Questionnaire.	450	1	30 min	225
Shigellosis case patients	Shigella Hypothesis Generating Questionnaire.	1500	1	45/60	1,125
Nontyphoidal *Salmonella,* STEC, *Vibrio,* or *Campylobacter* case patients whose bacterial isolates have concerning antimicrobial resistance.	NARMS SIRI Questionnaire Module 1.	305	1	15/60	77
Nontyphoidal *Salmonella* (except Newport strain), STEC, or *Vibrio* case patients whose bacterial isolates have concerning antimicrobial resistance.	NARMS SIRI Questionnaire Module 2.	130	1	10/60	22
Multidrug-resistant *Salmonella* Newport case patients.	NARMS SIRI Questionnaire Module 3.	125	1	15/60	32
Campylobacter case patients whose bacterial isolates have concerning antimicrobial resistance.	NARMS SIRI Questionnaire Module 4.	50	1	25/60	21
Salmonella Typhi or Paratyphi case patients whose bacterial isolates have concerning antimicrobial resistance.	NARMS SIRI Questionnaire Module 5.	50	1	20/60	17
Total					5,852

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2024–07287 Filed 4–4–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–24–0556; Docket No. CDC–2024–0025]

Proposed Data Collection Submitted for Public Comment and Recommendations

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), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Assisted Reproductive Technology (ART) Program Reporting System. This study is designed to collect information on ART cycles to publish information on pregnancy success rates as required under Section 2(a) of the Federal Clinic Success Rate and Certification Act (FCSRCA).

DATES: CDC must receive written comments on or before June 4, 2024.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2024–0025 by either of the following methods:

☐ *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.

☐ *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7118; Email: *omb@cdc.gov.*

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. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

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;

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; and

5. Assess information collection costs.

Proposed Project

Assisted Reproductive Technology (ART) Program Reporting System (OMB Control No. 0920–0556, Exp. 12/31/2024)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 2(a) of Public Law 102–493 (known as the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA), 42 U.S.C. 263a–1(a)) requires that each assisted reproductive technology (ART) program shall annually report to the Secretary through the Centers for Disease Control and Prevention: (1) pregnancy success rates achieved by such ART program; and (2) the identity of each embryo laboratory used by such ART program and whether the laboratory is certified or has applied for such certification under the Act. The required information is currently reported by ART programs to CDC as specified in the Assisted Reproductive Technology (ART) Program Reporting System (OMB Control No. 0920–0556, Exp. 12/31/2024). The current revision seeks to revise burden hour estimates, modify data elements collected, implement a new process for sharing data externally, and to extend OMB approval for a period of three years. The revised total burden estimate is higher than the previous approval, due to an increase in the utilization of ART in the United States and the number of reported cycles. Data elements collected will be modified to remove five data elements no longer needed and add one new data element to reflect current clinical practice. The average estimated burden for reporting information related to each cycle is not anticipated to change from the time burden previously approved (43 minutes). Data will be made available in the National Center for Health Statistics Research Data Center to increase accessibility of Assisted Reproductive Technology (ART) Program Reporting System data for secondary epidemiological analyses.

The currently approved program reporting system, also known as the National ART Surveillance System (NASS), collects information about all ART cycles initiated by ART programs in the United States. The start of an ART cycle is considered when a woman begins taking medication to stimulate egg production or begins monitoring with the intent of having embryos transferred. For each cycle, CDC collects information about the pregnancy outcome, as well as several data elements deemed by experts in the field to be important to explain variability in success rates across ART programs and individuals.

Each ART program reports its annual ART cycle data to CDC in mid-December. The annual data reporting consists of information about all ART cycles that were initiated in the previous calendar year. For example, ART programs that submit their data in mid-December 2021 will include all ART cycles that were initiated between January 1, 2020, and December 31, 2020.

Data elements and definitions currently in use reflect CDC's prior consultations with representatives of the Society for Assisted Reproductive Technology (SART), the American Society for Reproductive Medicine (ASRM), and RESOLVE: the National Infertility Association (a national, nonprofit consumer organization), as well as a variety of individuals with expertise and interest in this field.

The estimated number of respondents (ART programs or clinics) is 453, based on the number of clinics that provided information in 2021. This number is lower than the previous number of reporting clinics (456). The estimated average number of responses (ART cycles) per respondent is 913. The total burden estimate is higher than the previous approval due to an increase in the utilization of ART in the United States. Additionally, approximately 5–10% of responding clinics will be randomly selected each year to participate in data validation and quality control activities; an estimated 35 clinics will be selected to report validation data on 70 cycles each on average. Finally, respondents may provide feedback to CDC about the usability and utility of the reporting system. The option to participate in the feedback survey is presented to respondents when they complete their required data submission. Participation in the feedback survey is voluntary and is not required by the FCSRCA. CDC estimates that 50% of ART programs will participate in the feedback survey. Due to this lower response rate and reduced number of reporting clinics, CDC estimates 203 clinics will respond to voluntary feedback survey.

The collection of ART cycle information allows CDC to publish clinic-specific success rates annually as specified by the FCSRCA and to provide information needed by consumers. OMB approval is requested for three years. CDC requests approval for 297,352 annual burden hours. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
ART Program/Clinic	NASS Reporting Form	453	913	43/60	296,406
	Data Validation	35	70	23/60	939
	Feedback Survey	203	1	2/60	7
Total					297,352

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2024–07289 Filed 4–4–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–24–24EG; Docket No. CDC–2024–0024]

Proposed Data Collection Submitted for Public Comment and Recommendations

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), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Documenting outcomes associated with Persistent Tic Disorders (including Tourette Syndrome) in Children, Adolescents, and Young Adults through Surveillance. This study will collect data on the public health impact of persistent tic disorders from children and adolescents with tic disorders and their parents, as well as young adults with tic disorders.

DATES: CDC must receive written comments on or before June 4, 2024.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2024–0024 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

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. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

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;
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; and
5. Assess information collection costs.

Proposed Project

Documenting outcomes associated with Persistent Tic Disorders (including Tourette Syndrome) in Children, Adolescents, and Young Adults through Surveillance—New—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

There are an estimated 1.4 million people in the U.S. affected by persistent tic disorders (PTD), including Tourette syndrome (TS). To support people with these conditions, the impact of PTD/TS must be understood. Although some data on the impact of PTD/TS on social relationships and education are available, other potential outcomes associated with PTD/TS have not been well-documented; including associated costs, suicidality, health care transition, and the prevalence of co-occurring disorders and how co-occurring disorders modify these outcomes. Limited data are available on how these outcomes may differ among sub-populations (*e.g.,* by sex, race/ethnicity, age group, and geography [*e.g.,* urban/rural]).

This data collection aims to document priority outcomes including costs (*e.g.,* education level, employment, healthcare beyond those available in claims data), prevalence of suicidality risk, transition to adult healthcare, and the prevalence of co-occurring conditions and how they modify these outcomes among children and adolescents (4–17 years) and young adults (18–26 years) with PTD/TS. Data will be collected once from a participant (*i.e.,* individuals with PTD/TS and/or their caregiver), via a survey, and a clinical assessment of tic symptoms. All questions for the Tic Impact Surveillance Survey, the survey created for this surveillance project, were selected from national surveys or previously validated measures. This will allow us to compare estimates from the Tic Impact Surveillance Survey to external prevalence estimates for the same health indicators in US children, adolescents, and young adults in the general population and to previously published findings. Data will be used to inform where resources for families and healthcare providers (*e.g.,* professional trainings) are most needed to support people with PTD/TS and their families and to address health inequities among the population.

CDC requests OMB approval for an estimated 401 annual burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Parents of children 4–17 years with a persistent tic disorder.	Parent	225	1	45/60	169
Children 4–8 years with a persistent tic disorder.	Child 4–8	30	1	20/60	10
Children 9–11 years with a persistent tic disorder.	Child 9–11	45	1	45/60	34
Adolescents (teens) 12–17 years with a persistent tic disorder.	Adolescent	150	1	45/60	113
Adults (18–26 years) with a persistent tic disorder.	Adult	75	1	1	75
Total					401

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2024–07288 Filed 4–4–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of charter renewal.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), announces the renewal of the charter of the Advisory Board on Radiation and Worker Health (ABRWH).

FOR FURTHER INFORMATION CONTACT: Rashaun Roberts, Ph.D., Designated Federal Officer, Advisory Board on Radiation and Worker Health, Centers for Disease Control and Prevention, Department of Health and Human Services, 1090 Tusculum Avenue, Mailstop C–24, Cincinnati, Ohio 45226. Telephone: (513) 533–6800; Email: *ocas@cdc.gov.*

SUPPLEMENTARY INFORMATION: CDC is providing notice under 5 U.S.C. 1001–1014 of the renewal of the charter of the Advisory Board on Radiation and Worker Health, Centers for Disease Control and Prevention, Department of Health and Human Services. This charter has been renewed for a two-year period through March 22, 2026.

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–07301 Filed 4–4–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10545, CMS–R–246, CMS–43 and CMS–10842]

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 June 4, 2024.

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 *https://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**).

CMS–10545 Outcome and Assessment Information Set OASIS–E1

CMS–R–246 Medicare Advantage, Medicare Part D, and Medicare Fee-For-Service Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey

CMS–43 Application for Part A (Hospital Insurance) and Part B (Medical Insurance) for People with End-Stage Renal Disease

CMS–10842 End Stage Renal Disease (ESRD) Annual Home Dialysis within Nursing Home Survey Form

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Outcome and Assessment Information Set OASIS–E1; *Use:* This request is to modify the Outcome and Assessment Information Set (OASIS) that home health agencies (HHAs) are required to collect to participate in the Medicare program. The current OASIS version, OASIS–E, OMB control number 0938–1279, was approved by the OMB on November 30, 2022, and implemented on January 1, 2023. We are seeking OMB approval for the proposed revised OASIS data set, referred to hereafter as OASIS–E1, scheduled for implementation in the HH QRP on January 1, 2025. The OASIS–E1 includes changes related to addition of one item supporting an assessment-based quality measure (QM), removal of one item due to retirement of a QM, and removal of two data elements no longer used in the HH QRP or for other purposes in CMS programs. *Form Number:* CMS–10545 (OMB control number: 0938–1279); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 11,866; *Total Annual Responses:* 18,017,056; *Total Annual Hours:* 16,683,290. (For policy questions regarding this collection contact Jermama Keys at 410–786–7778).

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Advantage, Medicare Part D, and Medicare Fee-For-Service Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey; *Use:* CMS is required to collect and report information on the quality of health care services and prescription drug coverage available to persons enrolled in a Medicare health or prescription drug plan under provisions in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Specifically, the MMA under Sec. 1860D–4 (Information to Facilitate Enrollment) requires CMS to conduct consumer satisfaction surveys regarding Medicare prescription drug plans and Medicare Advantage plans and report this information to Medicare beneficiaries prior to the Medicare annual enrollment period. The Medicare CAHPS survey meets the requirement of collecting and publicly reporting consumer satisfaction information. The Balanced Budget Act of 1997 also requires the collection of information about fee-for-service plans. The CAHPS survey measures are incorporated into the Part C and D Star Ratings that are published on *www.medicare.gov* each fall to help consumers choose a Medicare plan. A subset of the CAHPS measures is also included in the *Medicare & You Handbook.* CAHPS information from MA contracts also feeds into the calculation of MA Quality Bonus Payment Ratings that are required by statute and regulation.

The primary purpose of the Medicare CAHPS surveys is to provide information to Medicare beneficiaries to help them make more informed choices among health and prescription drug plans available to them. Survey results are reported by CMS in the *Medicare & You Handbook* published each fall and on the Medicare Plan Finder website. Beneficiaries can compare CAHPS scores for each health and drug plan as well as compare MA and FFS scores when making enrollment decisions. The Medicare CAHPS also provides data to help CMS and others monitor the quality and performance of Medicare health and prescription drug plans and identify areas to improve the quality of care and services provided to enrollees of these plans. CAHPS data are included in the Medicare Part C & D Star Ratings and used to calculate MA Quality Bonus Payments. *Form Number:* CMS–R–246 (OMB control number: 0938–0732); *Frequency:* Yearly; *Affected Public:* Individuals and Households *Number of Respondents:* 794,500; *Total Annual Responses:* 794,500; *Total Annual Hours:* 192,265. (For policy questions regarding this collection contact Lauren Fuentes at 410–786–2290 or *lauren.fuentes@cms.hhs.gov*).

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Application for Part A (Hospital Insurance) and Part B (Medical Insurance) for People with End-Stage Renal Disease; *Use:* Form CMS–43 (Application for Part A (Hospital Insurance) and Part B (Medical Insurance) for People with End-Stage Renal Disease) supports section 226A(a) of the Social Security Act (the Act) and corresponding regulations at 42 CFR 406.7(c)(3) and 406.13.

Individuals with End-Stage Renal Disease (ESRD) have the opportunity to apply for Medicare benefits and obtain premium-free Part A if they meet certain criteria outlined in statute. Sections 226A of the Act authorizes entitlement for Medicare Hospital Insurance (Part A) if the individual with ESRD files an application for benefits and meets the requisite contributions through one's own employment or the employment of a related individual to meet the statutory definition of a ''currently insured'' individual outlined in section 214 of the Act. Further, for individuals who meet the requirements for premium-free Part A entitlement, Medicare coverage starts based on the dates in which the individual started dialysis treatment or had a kidney transplant. These statutory provisions are codified at 42 CFR 406.7(c)(3) and 407.13. *Form Number:* CMS–43 (OMB control number: 0938–0080); *Frequency:* Once; *Affected Public:* Individuals and Households *Number of Respondents:* 45,200; *Total Annual Responses:* 45,200; *Total Annual Hours:* 18,984. (For policy questions regarding this collection contact Candace Carter at

410–786–8466 or *Candace.Carter@cms.hhs.gov*).

4. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* End Stage Renal Disease (ESRD) Annual Home Dialysis within Nursing Home Survey Form; *Use:* The End Stage Renal Disease (ESRD) Network program is responsible to collect, validate, and analyze data as well as to evaluate the process by which facilities determine the appropriateness of patients for a treatment modality. Additional responsibilities of the ESRD Network program include encouraging participation in the placement of patients in a self-care setting, such as home hemodialysis or peritoneal dialysis, as described in Sec. 1881. [42 U.S.C. 1395rr] (c)(1)(A)(i)(2) of the Social Security Act. On September 21, 2018, CMS clarified guidance that residents in a nursing home facility can receive dialysis either administered and/or supervised by personnel who meet the criteria for training, and competency verification at 42 CFR 494.100(a) and (b) for providing dialysis. The provision of dialysis within a nursing home requires that the dialysis facility have an agreement with the nursing home. This guidance was reinforced and updated on March 22, 2023, in a memo to the State Survey Agency Directors titled, ''Guidance and Survey Process for Reviewing Home Dialysis Services in a Nursing Home REVISED''. Since the provision of dialysis within nursing homes is relatively new, CMS designed the CMS–10842 form to capture home modality information from dialysis facilities that provide dialysis within the nursing home in alignment with the Centers for Disease Control and Prevention (CDC).

The care provided to residents of a nursing home is of particular interest because of the fragile health state of the patient and the susceptibility to infection. Each facility certification/survey record represents one provider. CMS–10842 collects information on dialysis facilities providing home dialysis services within the nursing home related to the number of patients, setting of dialysis services provided, who is providing dialysis services, who is providing dressing changes to dialysis access, staff education and use of CDC Core Interventions used. The aggregate patient information is collected from each Medicare-approved home dialysis provider to identify the specialized needs of the ESRD community where home dialysis is provided in Long Term Care facilities. *Form Number:* CMS–10842 (OMB control number: 0938–NEW); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 7,726; *Total Annual Responses:* 7,726; *Total Annual Hours:* 5,795. (For policy questions regarding this collection contact Christina Goatee at 410–786–6689).

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–07202 Filed 4–4–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Proposed Information Collection Activity; Tribal Early Childhood Facilities Combined Application Guide (New Collection)

AGENCY: Office of Early Childhood Development, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Early Childhood Development (ECD), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting Office of Management and Budget (OMB) approval of the Tribal Early Childhood Facilities Combined Application Guide for joint applications for construction and major renovation projects using both Head Start and Child Care and Development Fund (CCDF) resources.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Funding for facilities under the CCDF is authorized by Section 658O(c)(6) of the Child Care and Development Block Grant (CCDBG) Act, 42 U.S.C. 9858(c)(6), and is managed by the Office of Child Care (OCC). Funding for Head Start facilities projects is authorized by 45 CFR part 1303 (Subpart E) Head Start Program Performance Standards and is managed by the Office of Head Start (OHS). The guide streamlines the process for Tribal CCDF Lead Agencies and American Indian and Alaska Native (AI/AN) Head Start programs submitting collaborative, joint applications to use federal CCDF and Head Start funds for facilities projects where funds can be used for reasonable costs and fees related to planning for a facilities project and to support the application development in tribal communities. Both funds aim to construct or improve early childhood facilities, often serving the same children, but application submission and review processes are currently unique to each respective funding stream. The proposed information collection will provide instructions to Tribal CCDF Lead Agencies and AI/AN Head Start programs on submitting joint plans for how proposed facilities projects will enable the programs to better serve current AI/AN families or increase enrollment currently limited by inadequate facilities. The guide will provide critical information and resources, so recipients understand the requirements of each program and develop plans that reflect the needs of their communities. Reducing and streamlining administrative burdens for tribal constituents follows policy priorities laid out in the 2022 HHS Equity Action Plan and is in alignment with Executive Order 14095—Executive Order on Increasing Access to High-Quality Care and Supporting Caregivers.

Respondents: AI/AN Head Start Facilities and Tribal CCDF Lead Agencies (information collection does not include direct interaction with individuals or families that receive the services).

Annual Burden Estimates: We estimate at most 10 applications per year and have estimated burden based on this maximum number.

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Tribal Early Childhood Facilities Application Guide	10	1	100	1,000

Authority: 42 U.S.C. 9858(c)(6); 45 CFR part 1303 Subpart E.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–07292 Filed 4–4–24; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–P–0105]

Determination That GLUCOTROL (Glipizide) Tablets, 5 Milligrams and 10 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that GLUCOTROL (glipizide) tablets, 5 milligrams (mg) and 10 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to these products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Swati Rawani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6221, Silver Spring, MD 20993–0002, 240–402–9917, *Swati.Rawani@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

GLUCOTROL (glipizide) tablets, 5 mg and 10 mg, are the subject of NDA 017783, held by Pfizer Inc., and initially approved on May 8, 1984. GLUCOTROL is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

In a letter dated June 30, 2022, Pfizer Inc., notified FDA that GLUCOTROL (glipizide) tablets, 5 mg and 10 mg, were being discontinued, and FDA moved these drug products to the ''Discontinued Drug Product List'' section of the Orange Book.

Graviti Pharmaceuticals Private Limited submitted a citizen petition dated January 3, 2024, Docket No. FDA–2024–P–0105, under 21 CFR 10.30, requesting that the Agency determine whether GLUCOTROL (glipizide) tablets, 5 mg and 10 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that GLUCOTROL (glipizide) tablets, 5 mg and 10 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that GLUCOTROL (glipizide) tablets, 5 mg and 10 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of GLUCOTROL (glipizide) tablets, 5 mg and 10 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.[1]

Accordingly, the Agency will continue to list GLUCOTROL (glipizide) tablets, 5 mg and 10 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to these drug products. Additional ANDAs for these drug products may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: April 2, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–07268 Filed 4–4–24; 8:45 am]

BILLING CODE 4164–01–P

[1] FDA previously determined that GLUCOTROL (glipizide) tablets, 2.5 mg, were not withdrawn from sale for reasons of safety or effectiveness (87 FR 28015, May 10, 2022).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0008]

Request for Nominations on Device Good Manufacturing Practice Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting that any industry organization interested in participating in the selection of a nonvoting industry representative to serve on the Device Good Manufacturing Practice Advisory Committee (DGMPAC) in the Center for Devices and Radiological Health notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative to fill an upcoming vacancy on DGMPAC. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for an upcoming vacancy effective with this notice.

DATES: Any industry organizations interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by *May 6, 2024* (see sections I and III of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by May 6, 2024.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nominations should be sent to Margaret Ames (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives should be submitted electronically by accessing FDA's Advisory Committee Membership Nomination Portal at *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Margaret Ames, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5213, Silver Spring, MD 20993–0002, 301–796–5960, *Margaret.Ames@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 520 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360j), as amended, provides that DGMPAC shall be composed of two representatives of interests of the device manufacturing industry. The Agency is requesting nominations for a nonvoting industry representative to fill an upcoming vacancy on DGMPAC. FDA is publishing a separate document announcing the request for notification for voting members on DGMPAC.

I. Function of DGMPAC

DGMPAC reviews proposed regulations, prior to their issuance, regarding good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacture, packaging, storage, installation, and servicing of devices, and makes recommendations regarding the feasibility and reasonableness of those proposed regulations. The committee also reviews and makes recommendations on proposed guidelines developed to assist the medical device industry in meeting the good manufacturing practice requirements and provides advice with regard to any petition submitted by a manufacturer for an exemption or variance from good manufacturing practice regulations.

II. Qualifications

Persons nominated for DGMPAC should possess appropriate qualifications to understand and contribute to the committee's work as described in the committee's function.

III. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry views should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry views for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within the 60 days, the Commissioner will select the nonvoting member to represent industry views.

IV. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address, telephone number, email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). Nominations must also specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups. Specifically, nominations for nonvoting representatives of industry interests are encouraged from the device manufacturing industry.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*) and 21 CFR part 14, relating to advisory committees.

Dated: April 2, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–07261 Filed 4–4–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0008]

Request for Nominations for Voting Members for the Patient Engagement Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is requesting nominations for voting members, excluding consumer and industry representatives, to serve on the Patient Engagement Advisory Committee (the Committee) in the Center for Devices and Radiological Health. Nominations will be accepted for upcoming vacancies effective with this notice. FDA seeks to include the views of members of all gender groups, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received on or before June 4, 2024, will be given first consideration for membership on the Committee. Nominations received after June 4, 2024, will be considered for nomination to the Committee as later vacancies occur.

ADDRESSES: All nominations for membership should be submitted electronically, by logging into the FDA Advisory Committee Membership Nomination Portal (*https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm*) and selecting Academician/Practitioner from the dropdown menu (regardless of whether Academician/Practitioner accurately describes the nominee), or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5407, Silver Spring, MD 20993–0002, 301–796–8398, email: *Letise.Williams@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members to fill upcoming vacancies on the Patient Engagement Advisory Committee. This notice does not include consumer and industry representative nominations. The Agency will publish two separate notices announcing the vacancy of a representative of consumer interests and vacancy of representatives of interests of the device manufacturing industry.

I. General Description of the Committee Duties

The Committee provides relevant skills and perspectives to improve communication of benefits, risks, and clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. The Committee performs its duties by identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy. The Committee provides advice on complex scientific issues related to medical devices, the regulation of devices, and their use by patients. Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient-reported outcomes, device-related quality of life measures, or health status issues are among the topics that may be considered by the Committee.

II. Criteria for Voting Members

The Committee consists of a core of nine voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities who are knowledgeable in areas such as clinical research, patient or caregiver experience, healthcare needs of patient groups in the United States, or are experienced in the work of patient and health professional organizations, scientific methodologies for patient-reported outcomes and other clinical outcome assessments, scientific methodologies for eliciting patient preferences, and strategies for communicating benefits, risks, and clinical outcomes to patients and research subjects, as well as other relevant areas. Members will be invited to serve for overlapping terms of up to 4 years. Prospective members should also have an understanding of the broad spectrum of patients in a particular disease area. Almost all non-Federal members of this Committee serve as Special Government Employees, with the exception of the representatives from industry.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the Committee. Self-nominations are also accepted. Nominations must include a cover letter; a current, complete résumé or curriculum vitae for each nominee, including current business and/or home address, telephone number, and email address if available; and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**). Nominations must specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*) and 21 CFR part 14, relating to advisory committees.

Dated: April 2, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–07254 Filed 4–4–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5257]

Robert Lance Shuffert: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Robert Lance Shuffert for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Shuffert was convicted of one felony count under Federal law for, with the intent to defraud and mislead, causing a drug to be misbranded while it was held for sale after shipment in interstate commerce. The factual basis supporting Mr. Shuffert's conviction, as described below, is conduct relating to

the importation into the United States of any drug or controlled substance. Mr. Shuffert was given notice of the proposed debarment and an opportunity to request a hearing to show why he should not be debarred. As of March 4, 2024 (30 days after receipt of the notice), Mr. Shuffert had not responded. Mr. Shuffert's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable April 5, 2024.

ADDRESSES: Any application by Mr. Shuffert for termination of debarment under section 306(d) of the FD&C Act (21 U.S.C. 335a(d)) may be submitted at any time as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

- *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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2023–N–5257. Received applications 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 an application with confidential information that you do not wish to be made publicly available, submit your application 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 your application. 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. Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket, 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 between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 240–402–8743, *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act permits FDA to debar a person from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On October 26, 2023, Robert Lance Shuffert was convicted as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the Southern District of Texas when the court accepted his plea of guilty and entered judgment against him for the offense of importing, causing misbranding, and distribution for sale a misbranded drug in violation of 21 U.S.C. 331(k) and 333(a)(2) (sections 301(k) and 303(a)(2) of the FD&C Act). The underlying facts supporting the conviction are as follows:

As contained in the Information from his case, Mr. Shuffert worked for Science Production Products LLC (SPP); although, in SPP's corporate filings with the Texas Secretary of State, he was listed as SPP's owner and operator, and someone else owned SPP and directed Mr. Shuffert's activities. SPP imported, created, marketed, and distributed for sale purported bodybuilding and dietary supplements, including, but not limited to, Selective Androgen Receptor Modulators (SARMs). SARMs are synthetic chemicals designed to mimic the effects of testosterone and other anabolic steroids. At the direction of SPP's owner, Mr. Shuffert operated SPP and SPP manufactured, marketed, and sold a SARM product called Ostarine MK–2866. This product was misbranded because it was labeled as a ''Research Product'' but was in fact intended to be used by humans as a drug to increase lean muscle mass and lose unwanted fat. Mr. Shuffert worked with others to import SARMs from China. Mr. Shuffert then would use the imported SARMs as components of a drug (Ostarine MK–2866) that he and others caused to become misbranded and then distributed for sale such misbranded drugs in the United States. Mr. Shuffert knowingly took steps to mislead and defraud the Government and consumers in the sale of SARMs, including Ostarine MK–2866.

FDA sent Mr. Shuffert, by certified mail, on January 30, 2024, a notice proposing to debar him for a 5-year period from importing or offering for import any drug into the United States. The proposal was based on FDA's finding under section 306(b)(3)(C) of the FD&C Act that Mr. Shuffert's felony conviction under Federal law for importing, causing misbranding, and distribution for sale a misbranded drug in violation of 21 U.S.C. 331(k) and 333(a)(2), was for conduct relating to the importation of any drug or controlled substance into the United States because Mr. Shuffert illegally imported SARMs from China, which he would use as components of a drug (Ostarine MK–2866) that he caused to become misbranded and then distributed for sale in the United States. Mr. Shuffert

knowingly took steps to mislead and defraud the Government and consumers in the sale of SARMs, including Ostarine MK–2866. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Shuffert's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Shuffert of the proposed debarment and offered him an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Shuffert received the proposal and notice of opportunity for a hearing on February 3, 2024. Mr. Shuffert failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Shuffert has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Shuffert is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act, the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Shuffert is a prohibited act.

Dated: April 2, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–07271 Filed 4–4–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1157]

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—General Topic

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on May 22, 2024, from 10 a.m. to 3:45 p.m. Eastern Time.

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform.

Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2024–N–1157. The docket will close May 21, 2024. 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 May 21, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before May 8, 2024, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–1157 for ''Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Jessica Seo, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–7699, email: *ODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. Amendments made by section 504 of the 2017 FDA Reauthorization Act to section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) required, for original applications submitted on or after August 18, 2020, pediatric investigations of certain targeted cancer drugs with new active ingredients, based on molecular mechanism of action rather than clinical indication. The Committee will discuss perspectives relating to implementation of this legislation and its impact on pediatric cancer drug development to date.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before May 8, 2024, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 30, 2024. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 1, 2024.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Jessica Seo (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: April 2, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–07273 Filed 4–4–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Final Action Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice sets forth final changes to *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* as initially outlined in a **Federal Register** notice issued on August 10, 2023. Following solicitation of public comments, the NIH is amending the *NIH Guidelines* to include specific considerations and requirements for conducting research

involving gene drive modified organisms (GDMOs) in contained research settings. NIH is updating the *NIH Guidelines* to clarify minimum containment requirements, provide considerations for performing risk assessments, and define additional institutional responsibilities regarding Institutional Biosafety Committees (IBCs) and Biological Safety Officers (BSOs).

DATES: Changes outlined in this notice will be implemented on September 30, 2024.

FOR FURTHER INFORMATION CONTACT: Caroline Young, ScM, Acting Director of the Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy, Office of Science Policy, at (301) 496–9838 or email at *SciencePolicy@od.nih.gov*.

SUPPLEMENTARY INFORMATION: In a **Federal Register** notice issued on August 10, 2023 (88 FR 54332), NIH proposed a series of actions to the NIH Guidelines for public comment. NIH is amending the *NIH Guidelines* to ensure the continued responsible research involving GDMOs in contained research settings. Specifically, the *NIH Guidelines* will be amended to:

1. clarify minimum containment requirements for research involving GDMOs;
2. provide considerations for risk assessment;
3. define additional institutional responsibilities for IBCs and BSOs.

In addition to the amendments related to contained research involving GDMOs, the *NIH Guidelines* will also be amended to:

1. replace the term ''helper viruses'' with the broader term ''helper systems''; and
2. reclassify WNV and SLEV as risk group 2 agents for consistency with containment guidance provided in the BMBL.

The revisions apply to GDMO research in contained settings, which is subject to the *NIH Guidelines.* These revisions are consistent with the recommendations of the Novel and Exceptional Technology Research Advisory Committee report, *Gene Drives in Biomedical Research* (NExTRAC Report). NIH does not currently support research involving field release of GDMOs and the *NIH Guidelines* pertain to contained research; accordingly, no changes regarding potential field release are included in this Notice. NIH is also revising the *NIH Guidelines* to harmonize with the 6th edition of the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) regarding the Risk Group (RG) categorization of West Nile Virus (WNV) and Saint Louis Encephalitis Virus (SLEV).

Overview of Comments Received in Response to NIH's Proposal To Amend the NIH Guidelines (88 FR 54332)

The NIH received 28 comments (available at *https://osp.od.nih.gov/wp-content/uploads/2023/11/RFI_Nucleic_Final_508.pdf*) submitted by individuals from the general public, academic institutions, and professional or membership organizations in response to the proposal to amend the *NIH Guidelines* posted to the **Federal Register** on August 10, 2023. All comments were reviewed and considered by the NIH. Most comments did not express general concerns with the proposed amendments, but many included comments or questions on specific sections. These comments, along with NIH responses, are summarized below.

Several of the comments requested additional guidance or resources to accompany any changes. As a source of information in addition to that in the *NIH Guidelines,* the NIH will provide a supplementary reference document, *Biosafety Considerations for Contained Research Involving Gene Drive Modified Organisms,* that institutions, investigators, and the biosafety community can reference as they consider conducting contained gene drive research. The reference document is intended to organize the relevant sections of the *NIH Guidelines* in an accessible format and to provide some additional information and resources. It will be available on the NIH Office of Science Policy (OSP) *NIH Guidelines* website, along with Frequently Asked Questions.

Definition of ''*gene drive*'' *in Section I–E–7.* Several comments requested additional clarification of the definition and that the definition specify ''engineered'' gene drives to exclude natural gene drives. Under the scope of *NIH Guidelines,* only contained research with gene drives involving recombinant or synthetic nucleic acids would be subject to the *NIH Guidelines.* The definition language is based on the definition in the NExTRAC report, *Gene Drives in Biomedical Research.* Other comments asked whether certain research with prokaryotes or viruses could be considered to involve GDMOs. While gene drive technologies are usually applied to sexually reproducing organisms, the risk assessment section of the *NIH Guidelines* will include guidance on the consideration of modifications with properties similar to a gene drive. The supplementary reference document will include sources for additional information on gene drive technologies and capabilities.

Section II–A–3 Risk Assessment. In response to comments seeking additional risk assessment guidance, in particular regarding relevant biosafety data, the reference document will include links to sources with additional information including the NExTRAC report, the National Academy of Sciences report, *Gene Drives on the Horizon,* and other relevant literature sources.

Section III–D Containment

Regarding the requirement of a minimum of biosafety level 2 (BL2) containment for work with GDMOs, several comments asked about appropriate BL2 containment for specific species. Gene drive research may be conducted in a broad range of species, and institutions may wish to consult containment guidance tailored to the specific species or type of organism utilized in a particular protocol. For work with arthropods, the *NIH Guidelines* will be amended to reference the *Arthropod Containment Guidelines* and *Addendum 1 Containment Practices for Arthropods Modified with Engineered Transgenes Capable of Gene Drive.* The reference document will include sources for additional species. In particular, there were comments about *Saccharomyces* and *Kluyveromyces* Host-Vector Systems. The amendments will only affect research involving host vector systems modified by a gene drive and does not pertain to other yeast research.

Other comments requested a process for handling requests to lower containment levels for research involving GDMOs. As with requests to lower containment for research involving infectious agents outlined in Section IV–C–b–(2)–(a), OSP will consider containment lowering requests for research involving GDMO on a case-by-case basis.

Section III–D and III–E. Comments were supportive of the terminology shift from ''helper virus'' to ''helper system,'' but several asked that the examples of helper systems that were included in the **Federal Register** notice also be included in the *NIH Guidelines.* To provide that information, the preamble to III–D–3 will state: ''The potential for reversion or generation of replication competent virus should be considered when generating or using defective viruses or vectors in the presence of helper systems (*e.g.,* helper viruses, packaging cell lines, transient transfection systems, replicon systems).''

Section III–E–3 Experiments Involving Transgenic Rodents

Several comments asked whether NIH was proposing to expand Section III–E–3 to include the use of transgenic rodents. There are two instances where transgenic rodents are specifically exempted from the *NIH Guidelines.* Appendix C–VII exempts the purchase or transfer of transgenic rodents and Appendix C–VIII exempts the generation of BL1 rodents by breeding. The use of exempt rodents remains exempt unless the subsequent research involves the use of recombinant or synthetic nucleic acid molecules. The language added to III–E–3 is not an expansion to include the use of *de novo* generated rodents covered under that section. Rodents covered under III–E–3 are not exempt and, as such, their subsequent use is not exempt. The inclusion of the language referring to the use of such rodents is intended to clarify that their subsequent use is not exempt.

Section IV Roles and Responsibilities and V–N. Several comments asked for clarification regarding the requirement for adequate expertise on IBCs reviewing GDMO research including consideration of ecological impacts. Consistent with expectations in the *NIH Guidelines* for the review of research with plants, animals, or human research participants, appropriate expertise regarding ecological impacts may be provided by members of the IBC or ad hoc consultants. An ad hoc consultant with expertise in ecological impacts would only be needed for review of specific GDMO research and, if an institution has multiple IBCs, would only be required to serve on the specific IBC reviewing such research. An ad hoc consultant may be from a partner or unrelated institution and does not need to be local to the institution.

Several comments addressed the additional requirement for a biological safety officer (BSO) to be appointed if research involving GDMOs is to be conducted. Some commenters interpreted this language to mean that a BSO must be appointed if the institution engages in any BL2 research. To clarify, a BSO must be appointed if the institution engages in recombinant or synthetic nucleic acid molecule research that involves GDMOs. Section IV–B–1–c will be revised to clarify this requirement. Others commented on the qualifications of a BSO and the reference to the *Laboratory Safety Monograph*. The duties of a BSO are specifically outlined in Section IV–B–3 of the *NIH Guidelines.*

Appendix B Classification of Human Etiologic Agents on the Basis of Hazard. All comments regarding this proposed change supported the reclassification of West Nile Virus and Saint Louis Encephalitis virus (SLEV) as risk group 2 agents to harmonize with guidance provided by the BMBL. One comment noted that SLEV was improperly classified as an alphavirus. Appendix B will be amended to classify SLEV as a flavivirus. As minor actions under the *NIH Guidelines,* Appendix B–IV–D Risk Group 4 Viral Agents will be amended from ''Hemorrhagic fever agents and viruses as yet undefined'' to ''Hemorrhagic fever viruses as yet undefined'' to prevent possible misinterpretation that all undefined viruses require RG4 containment, and the listing of Ebola and Marburg virus will be pluralized to harmonize with recent changes in taxonomy nomenclature to cover multiple viruses. The amendment to ''Ebola viruses'' and ''Marburg viruses'' will clarify that the virus name applies to the multiple species.

Amendments to the NIH Guidelines

Section I–E will be amended as follows:

Section I–E. General Definitions

Section I–E–7. ''Gene drive'' is defined as a technology whereby a particular heritable element biases inheritance in its favor, resulting in the heritable element becoming more prevalent than predicted by Mendelian laws of inheritance in a population over successive generations.

Section II–A–3 will be amended as follows:

Section II–A–3. Comprehensive Risk Assessment

In deciding on the appropriate containment for an experiment, the first step is to assess the risk of the agent itself. Appendix B, Classification of Human Etiologic Agents on the Basis of Hazard, classifies agents into Risk Groups based on an assessment of their ability to cause disease in humans and the available treatments for such disease. Once the Risk Group of the agent is identified, this should be followed by a thorough consideration of how the agent is to be manipulated. Factors to be considered in determining the level of containment include agent factors such as: virulence, pathogenicity, infectious dose, environmental stability, route of spread, communicability, operations, quantity, availability of vaccine or treatment, and gene product effects such as toxicity, physiological activity, and allergenicity. Any strain that is known to be more hazardous than the parent (wild-type) strain should be considered for handling at a higher containment level. Certain attenuated strains or strains that have been demonstrated to have irreversibly lost known virulence factors may qualify for a reduction of the containment level compared to the Risk Group assigned to the parent strain (see Section V–B, Footnotes and References of Sections I–IV).

While the starting point for the risk assessment is based on the identification of the Risk Group of the parent agent, as technology moves forward, it may be possible to develop an organism containing genetic sequences from multiple sources such that the parent agent may not be obvious. In such cases, the risk assessment should include at least two levels of analysis. The first involves a consideration of the Risk Groups of the source(s) of the sequences and the second involves an assessment of the functions that may be encoded by these sequences (*e.g.,* virulence or transmissibility). It may be prudent to first consider the highest Risk Group classification of all agents that are the source of sequences included in the construct. Other factors to be considered include the percentage of the genome contributed by each parent agent and the predicted function or intended purpose of each contributing sequence. The initial assumption should be that all sequences will function as they did in the original host context.

The Principal Investigator and Institutional Biosafety Committee must also be cognizant that the combination of certain sequences in a new biological context may result in an organism whose risk profile could be higher than that of the contributing organisms or sequences. The synergistic function of these sequences may be one of the key attributes to consider in deciding whether a higher containment level is warranted, at least until further assessments can be carried out. A new biosafety risk may occur with an organism formed through combination of sequences from a number of organisms or due to the synergistic effect of combining transgenes that results in a new phenotype.

A final assessment of risk based on these considerations is then used to set the appropriate containment conditions for the experiment (see Section II–B, Containment). The appropriate containment level may be equivalent to the Risk Group classification of the agent or it may be raised or lowered as a result of the above considerations. The Institutional Biosafety Committee must

approve the risk assessment and the biosafety containment level for recombinant or synthetic nucleic acid experiments described in Sections III–A, Experiments that Require NIH Director Approval and Institutional Biosafety Committee Approval, Before Initiation; III–B, Experiments that Require NIH OSP and Institutional Biosafety Committee Approval Before Initiation; III–C, Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation; III–D, Experiments that Require Institutional Biosafety Committee Approval Before Initiation.

Research involving gene drive modified organisms may require risk assessments that incorporate a broader scope of considerations because of greater uncertainty of the technology and potential uncertainty of the impact of the newly modified organism. Specific attention must be paid to risks of an unintended release from the laboratory and the potential impact on humans, other populations of organisms, and the environment.

Considerations for conducting risk assessments for research involving gene drive modified organisms might include:

1. The specific types of manipulations based on:

a. Function or intended function of the genetic/gene drive construct (*i.e.,* a designed or engineered assembly of sequences);

b. Source of the genetic material (*e.g.,* sequences of transgenes) in the construct;

c. The modifications to the construct;

d. Whether it is possible to predict the consequences of a construct, including the recognition of an unintended gene drive (*i.e.,* construct not specifically designed as a gene drive but nonetheless having properties of a gene drive) and the possible consequences of escape into the environment;

e. The potential ability of the gene drive to spread or persist in local populations;

2. Options for approaches to risk mitigation for specific types of risks in experiments or when dealing with a high degree of uncertainty about risks;

3. Considerations for implementing more stringent containment measures until biosafety data are accrued to support lowering containment.

Careful consideration should be given to the types of manipulation planned for some higher Risk Group agents. For example, the RG2 dengue viruses may be cultured under the Biosafety Level (BL) 2 containment (see Section II–B); however, when such agents are used for animal inoculation or transmission studies, a higher containment level is recommended. Similarly, RG3 agents such as Venezuelan equine encephalomyelitis and yellow fever viruses should be handled at a higher containment level for animal inoculation and transmission experiments.

Individuals working with human immunodeficiency virus (HIV), hepatitis B virus (HBV) or other bloodborne pathogens should consult the applicable Occupational Safety and Health Administration (OSHA) regulation, 29 CFR 1910.1030, and OSHA publication 3127 (1996 revised). BL2 containment is recommended for activities involving all blood-contaminated clinical specimens, body fluids, and tissues from all humans, or from HIV- or HBV-infected or inoculated laboratory animals. Activities such as the production of research-laboratory scale quantities of HIV or other bloodborne pathogens, manipulating concentrated virus preparations, or conducting procedures that may produce droplets or aerosols, are performed in a BL2 facility using the additional practices and containment equipment recommended for BL3. Activities involving industrial scale volumes or preparations of concentrated HIV are conducted in a BL3 facility, or BL3 Large Scale if appropriate, using BL3 practices and containment equipment.

Exotic plant pathogens and animal pathogens of domestic livestock and poultry are restricted and may require special laboratory design, operation and containment features not addressed in *Biosafety in Microbiological and Biomedical Laboratories* (see Section V–C, Footnotes and References of Sections I through IV). For information regarding the importation, possession, or use of these agents see Sections V–G and V–H, Footnotes and References of Sections I through IV.

A portion of Section III–C–1 will be amended as follows:

Section III–C–1. Experiments Involving the Deliberate Transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA Derived From Recombinant or Synthetic Nucleic Acid Molecules, Into One or More Human Research Participants

Human gene transfer is the deliberate transfer into human research participants of either:

1. Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or

2. Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria:

a. Contain more than 100 nucleotides; or

b. Possess biological properties that enable introduction of stable genetic modifications into the genome (*e.g.,* cis elements involved in integration, gene editing); or

c. Have the potential to replicate in a cell; or

d. Can be translated or transcribed.

Section III–F–1 will be amended as follows:

Section III–F–1 Exempt Experiments

Section III–F–1. Those synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (*e.g.,* oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (2) are not designed to introduce a stable genetic modification, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. If a synthetic nucleic acid is deliberately transferred into one or more human research participants and meets the criteria of Section III–C, it is not exempt under this section.

Section III–D–4 will be amended as follows:

Section III–D–4. Experiments Involving Whole Animals

This section covers experiments involving deliberate transfer of recombinant or synthetic nucleic acid molecules, DNA or RNA derived from recombinant or synthetic nucleic acid molecules, or recombinant or synthetic nucleic acid molecule-modified microorganisms into whole animals and experiments involving whole animals in which the animal's genome has been altered by recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ-line (transgenic animals). Experiments involving gene drive modified animals or experiments involving viable recombinant or synthetic nucleic acid molecule-modified microorganisms, except for viruses that are only vertically transmitted, may *not* be conducted at BL1–N containment. A minimum containment of BL2 or BL2–N is required (see Section III–D–8).

Caution—Special care should be used in the evaluation of containment conditions for some experiments with transgenic animals. For example, such experiments might lead to the creation of novel mechanisms (*e.g.,* a gene drive; refer to Section III–D–8) or increased transmission of a recombinant pathogen

or production of undesirable traits in the host animal. In such cases, serious consideration should be given to increasing the containment conditions.

Section III–D–4–a. Recombinant or synthetic nucleic acid molecules, or DNA or RNA molecules derived therefrom, from any source except for greater than two-thirds of eukaryotic viral genome may be transferred to any non-human vertebrate or any invertebrate organism and propagated under conditions of physical containment comparable to BL1 or BL1–N and appropriate to the organism under study (see Section V–B, Footnotes and References of Sections I–IV). Animals that contain sequences from viral vectors, which do not lead to transmissible infection either directly or indirectly as a result of complementation or recombination in animals, may be propagated under conditions of physical containment comparable to BL1 or BL1–N and appropriate to the organism under study. Experiments involving the introduction of other sequences from eukaryotic viral genomes into animals are covered under Section III–D–4–b, Experiments Involving Whole Animals. For experiments involving recombinant or synthetic nucleic acid molecule-modified Risk Groups 2, 3, 4, or restricted organisms, see Sections V–A, V–G, and V–L, Footnotes and References of Sections I–IV. It is important that the investigator demonstrate that the fraction of the viral genome being utilized does not lead to productive infection. A U.S. Department of Agriculture permit is required for work with plant or animal pathogens (see Section V–G, Footnotes and References of Sections I–IV).

Section III–D–4–b. For experiments involving recombinant or synthetic nucleic acid molecules, or DNA or RNA derived therefrom, involving whole animals, including transgenic animals, and not covered by Section III–D–1, Experiments Using Human or Animal Pathogens (Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems), or Section III–D–4–a, the appropriate containment shall be determined by the Institutional Biosafety Committee. Experiments involving gene drive modified animals generated by recombinant or synthetic nucleic acid molecules shall be conducted at a minimum of BL2 or BL2–N (see Section III–D–8).

Section III–D–4–c. Exceptions under Section III–D–4, Experiments Involving Whole Animals

Section III–D–4–c–(1). Experiments involving the generation of transgenic rodents that require BL1 containment are described under Section III–E–3, Experiments Involving Transgenic Rodents.

Section III–D–4–c–(2). The purchase or transfer of BL1 transgenic rodents is exempt from the *NIH Guidelines* under Section III–F, Exempt Experiments (see Appendix C–VII, The Purchase or Transfer of Transgenic Rodents).

Section III–D–4–c–(3). Experiments involving the generation or use of gene drive modified animals require a minimum of BL2 containment and are covered under III–D–8, Experiments Involving Gene Drive Modified Organisms.

A portion of Section III–D–5 will be amended as follows:

Section III–D–5. Experiments Involving Whole Plants

Experiments to genetically engineer plants by recombinant or synthetic nucleic acid molecule methods, to use such plants for other experimental purposes (*e.g.,* response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant or synthetic nucleic acid molecules, may be conducted under the containment conditions described in Sections III–D–5–a through III–D–5–e. If experiments involving whole plants are not described in Section III–D–5 and do not fall under Sections III–A, III–B, III–D or III–F, they are included in Section III–E. Experiments involving the generation or use of gene drive modified organisms require a minimum of BL2 containment and are described under Section III–D–8, Experiments Involving Gene Drive Modified Organisms.

Section III–D–8 will be added as follows:

Section III–D–8. Experiments Involving Gene Drive Modified Organisms

Experiments involving gene drive modified organisms generated by recombinant or synthetic nucleic acid molecules shall be conducted at a minimum of Biosafety Level (BL) 2, BL2–N (Animals) or BL2–P (plant) containment.

A portion of Section III–E–3 will be amended as follows:

Section III–E–3. Experiments Involving Transgenic Rodents

This section covers experiments involving the generation or use of rodents in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ-line (transgenic rodents). Only experiments that require BL1 containment are covered under this section; experiments that require BL2, BL3, or BL4 containment are covered under Section III–D–4, Experiments Involving Whole Animals or Section III–D–8, Experiments Involving Gene Drive Modified Organisms.

Section IV–B–1–c will be amended as follows:

Section IV–B–1–c. Appoint a Biological Safety Officer (who is also a member of the Institutional Biosafety Committee) if the institution: (i) conducts recombinant or synthetic nucleic acid molecule research at Biosafety Level (BL) 3 or BL4, (ii) engages in large-scale (greater than 10 liters) research or (iii) conducts any research involving gene drive modified organisms, which all must be conducted at BL2 or higher containment. The Biological Safety Officer carries out the duties specified in Section IV–B–3.

Section IV–B–2–a–(1) will be amended as follows:

Section IV–B–2–a–(1). The Institutional Biosafety Committee must comprise no fewer than five members so selected that they collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology and the capability to assess the safety of recombinant or synthetic nucleic acid molecule research and to identify any potential risk to public health or the environment. At least two members shall not be affiliated with the institution (apart from their membership on the Institutional Biosafety Committee) and who represent the interest of the surrounding community with respect to health and protection of the environment (*e.g.,* officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community). The Institutional Biosafety Committee shall include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix L, Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Plants, require prior approval by the Institutional Biosafety Committee. The Institutional Biosafety Committee shall include at least one scientist with expertise in animal containment principles when experiments utilizing Appendix M, Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals, require Institutional Biosafety Committee prior approval. When the institution conducts research involving

gene drive modified organisms, the institution must ensure that the Institutional Biosafety Committee has adequate expertise (*e.g.,* specific species containment, ecological or environmental risk assessment) using ad hoc consultants if necessary. When the institution conducts recombinant or synthetic nucleic acid molecule research at BL3, BL4, or Large Scale (greater than 10 liters) or research involving gene drive modified organisms, a Biological Safety Officer is mandatory and shall be a member of the Institutional Biosafety Committee (see Section IV–B–3, Biological Safety Officer). When the institution conducts research with gene drive modified organisms, the impact on ecosystems should be assessed by the Institutional Biosafety Committee (see Section V–N, Footnotes and References of Sections I–IV). When the institution participates in or sponsors recombinant or synthetic nucleic acid molecule research involving human research participants, the institution must ensure that the Institutional Biosafety Committee has adequate expertise and training (using ad hoc consultants if necessary). Institutional Biosafety Committee approval must be obtained from the clinical trial site. Section IV–B–3, Biological Safety Officer (BSO), will be amended as below in Section IV–B–3–a along with the addition of a new Section IV–B–3–c and re-lettering of the current Section IV–B–3–c to IV–B–3–d as follows:

Section IV–B–3–a. The institution shall appoint a Biological Safety Officer if it engages in large-scale research or production activities involving viable organisms containing recombinant or synthetic nucleic acid molecules. The Biological Safety Officer shall be a member of the Institutional Biosafety Committee.

Section IV–B–3–c. The institution shall appoint a Biological Safety Officer if it engages in recombinant or synthetic nucleic acid molecule research that involves gene drive modified organisms. The Biological Safety Officer shall be a member of the Institutional Biosafety Committee.

A new footnote and reference for Sections I through IV will be to be added as follows:

Section V–N. Determination of whether a gene drive modified organism has a potential for serious detrimental impact on managed (agricultural, forest, grassland) or natural ecosystems should be made by the Principal Investigator and the Institutional Biosafety Committee, in consultation with scientists knowledgeable of gene drive technology, and of the environment, and ecosystems in the geographic area of the research.

Appendices C–III–A Exceptions and C–IV–A Exceptions will be amended as follows:

The following categories are not exempt from the *NIH Guidelines:* (i) experiments described in Section III–B, which require NIH OSP and Institutional Biosafety Committee approval before initiation; (ii) experiments involving DNA from Risk Groups 3, 4, or restricted organisms (see Appendix B, Classification of Human Etiologic Agents on the Basis of Hazard, and Sections V–G and V–L, Footnotes and References of Sections I through IV) or cells known to be infected with these agents may be conducted under containment conditions specified in Section III–D–2 with prior Institutional Biosafety Committee review and approval; (iii) large-scale experiments (*e.g.,* more than 10 liters of culture), (iv) experiments involving the deliberate cloning of genes coding for the biosynthesis of molecules toxic for vertebrates (see Appendix F, Containment Conditions for Cloning of Genes Coding for the Biosynthesis of Molecules Toxic for Vertebrates), and (v) experiments involving gene drive modified organisms (Section III–D–8).

Appendix G–III–A will be amended as follows:

Appendix G–III–A. Biosafety in Microbiological and Biomedical Laboratories, 6th edition, U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, Atlanta, Georgia, and National Institutes of Health, Bethesda, Maryland.

Appendix G–III–B will be amended as follows:

Appendix G–III–B. Arthropod Containment Guidelines, Version 3.2, 2019, and *Addendum 1 Containment Practices for Arthropods Modified with Engineered Transgenes Capable of Gene Drive,* 2022, American Committee of Medical Entomology, American Society of Tropical Medicine and Hygiene, Arlington, Virginia.

Appendix L–III–C will be amended as follows:

Appendix L–III–C. Biological Containment Practices (Macroorganisms)

Appendix L–III–C–1. Effective dissemination of arthropods and other small animals can be prevented by using one or more of the following procedures: (i) use non-flying, flight-impaired, or sterile arthropods; (ii) use non-motile or sterile strains of small animals; (iii) conduct experiments at a time of year that precludes the survival of escaping organisms; (iv) use animals that have an obligate association with a plant that is not present within the dispersal range of the organism; or (v) prevent the escape of organisms present in run-off water by chemical treatment or evaporation of run-off water. Containment for arthropods is described in the *Arthropod Containment Guidelines* and *Addendum 1 Containment Practices for Arthropods Modified with Engineered Transgenes Capable of Gene Drive* (see Appendix G–III–B).

Appendix M–III–D will be amended as follows:

Appendix M–III–D. Research with animals, which may not appropriately be conducted under conditions described in Appendix M, may be conducted safely by applying practices routinely used for controlled culture of these biota. In aquatic systems, for example, BL1 equivalent conditions could be met by utilizing growth tanks that provide adequate physical means to avoid the escape of the aquatic species, its gametes, and introduced exogenous genetic material. A mechanism shall be provided to ensure that neither the organisms nor their gametes can escape into the supply or discharge system of the rearing container (*e.g.,* tank, aquarium, etc.). Acceptable barriers include appropriate filtration, irradiation, heat treatment, chemical treatment, etc. Moreover, the top of the rearing container shall be covered to avoid escape of the organism and its gametes. In the event of tank rupture, leakage, or overflow, the construction of the room containing these tanks should prevent the organisms and gametes from entering the building's drains before the organism and its gametes have been inactivated.

Other types of animals (*e.g.,* nematodes, arthropods, and certain forms of smaller animals) may be accommodated by using the appropriate BL1 through BL4 or BL1–P through BL4–P containment practices and procedures as specified in Appendices G and L. Containment for arthropods is described in the *Arthropod Containment Guidelines* and *Addendum 1 Containment Practices for Arthropods Modified with Engineered Transgenes Capable of Gene Drive* (see Appendix G–III–B).

Section III–D–3 will be amended as follows:

Section III–D–3. Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of a Helper System in Tissue Culture Systems

Caution: The potential for reversion or generation of replication competent virus should be considered when generating or using defective viruses or vectors in the presence of helper systems (*e.g.,* helper viruses, packaging cell lines, transient transfection systems, replicon systems). Special care should be used in the evaluation of containment levels for experiments which are likely to either enhance the pathogenicity (*e.g.,* insertion of a host oncogene) or to extend the host range (*e.g.,* introduction of novel control elements) of viral vectors under conditions that permit a productive infection. In such cases, serious consideration should be given to increasing physical containment by at least one level.

Note: Recombinant or synthetic nucleic acid molecules or nucleic acid molecules derived therefrom, which contain less than two-thirds of the genome of any eukaryotic virus (all viruses from a single Family (see Section V–J, *Footnotes and References of Sections I–IV*) being considered identical (see Section V–K, *Footnotes and References of Sections I–IV*)), are considered defective and may be used in the absence of helper systems under the conditions specified in Section III–E–1, *Experiments Involving the Formation of Recombinant or Synthetic Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus.*

Section III–D–3–a. Experiments involving the use of infectious or defective Risk Group 2 viruses (see Appendix B–II, *Risk Group 2 Agents*) in the presence of a helper system may be conducted at BL2.

Section III–D–3–b. Experiments involving the use of infectious or defective Risk Group 3 viruses (see Appendix B–III–D, *Risk Group 3 (RG3)—Viruses and Prions*) in the presence of a helper system may be conducted at BL3.

Section III–D–3–c. Experiments involving the use of infectious or defective Risk Group 4 viruses (see Appendix B–IV–D, *Risk Group 4 (RG4)—Viral Agents*) in the presence of a helper system may be conducted at BL4.

Section III–D–3–d. Experiments involving the use of infectious or defective restricted poxviruses (see Sections V–A and V–L, *Footnotes and References of Sections I–IV*) in the presence of a helper system shall be determined on a case-by-case basis following NIH OSP review. A U.S. Department of Agriculture permit is required for work with plant or animal pathogens (see Section V–G, *Footnotes and References of Sections I–IV*).

Section III–D–3–e. Experiments involving the use of infectious or defective viruses in the presence of a helper system which are not covered in Sections III–D–3–a through III–D–3–d may be conducted at BL1.

Section III–E–1 will be amended as follows:

Section III–E–1. Experiments Involving the Formation of Recombinant or Synthetic Nucleic Acid Molecules Containing No More Than Two-Thirds of the Genome of Any Eukaryotic Virus

Recombinant or synthetic nucleic acid molecules containing no more than two-thirds of the genome of any eukaryotic virus (all viruses from a single Family being considered identical [see Section V–J, *Footnotes and References of Sections I–IV]*) may be propagated and maintained in cells in tissue culture using BL1 containment. For such experiments, it must be demonstrated that the cells lack a helper system for the specific Families of defective viruses being used. If a helper system is present, procedures specified under Section III–D–3, *Experiments Involving the Use of Infectious Animal or Plant DNA or RNA Viruses or Defective Animal or Plant DNA or RNA Viruses in the Presence of Helper Systems in Tissue Culture Systems,* should be used. The DNA may contain fragments of the genome of viruses from more than one Family but each fragment shall be less than two-thirds of a genome.

Appendix B–II–D will be amended as follows:

Appendix B–II–D. Risk Group 2 (RG2)—Viruses

Flaviviruses—Group B Arboviruses
—Saint Louis Encephalitis Virus (SLEV)
—West Nile virus (WNV)

Appendix B–IV–D Risk Group 4 (RG4)—Viruses

Filoviruses
—Ebola viruses
—Marburg viruses
Hemorrhagic fever viruses as yet undefined

Dated: March 25, 2024.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2024–07082 Filed 4–4–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Planning Grants (R34 Clinical Trial Not Allowed).

Date: May 1, 2024.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Michael M. Opata, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22, Rockville, MD 20852, 240–627–3319, *michael.opata@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 2, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–07277 Filed 4–4–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as

amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group; Fellowships in Kidney, Urology, and Hematology DDK–G Fellowships in Kidney, Urology, and Hematology.

Date: June 12, 2024.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015 (In-Person).

Contact Person: Xiaodu Guo, M.D., Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7023, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–4719, *guox@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: April 2, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–07279 Filed 4–4–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

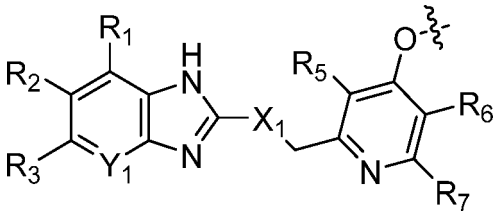
ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by contacting Michael Shmilovich, Esq, MS, CLP; 301–435–5019; *michael.shmilovich@nih.gov,* at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892–2479. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: This notice is in accordance with 35 U.S.C. 209 and 37 CFR part 404. Technology description follows. Prazole-Based Antiviral Therapeutics:

Available for licensing and commercial development is a patent estate that covers prazole based compounds and their methods of use as antiviral therapeutics. Prazoles are benzimidazole derivatives generally marketed as stomach-acid reducers, owing to their ability to inhibit the H+/K+ ATPases (proton pumps) of the parietal cells in the stomach epithelium. Prazoles can inhibit the egress of several viral targets: HIV–1, HSV–1 and –2, MAYV, and EBV by interfering with the ESCRT complex in the formation of exosomes. In that respect, the target for inhibition of these viruses is Tumor susceptibility gene 101 (Tsg101), a member of the ESCRT–I complex. The N-terminal ubiquitin E2 variant (UEV) domain of Tsg101 has both ubiquitin and P[T/S]AP motif binding sites, where the prazole binds to C73 in the middle of the ubiquitin-binding site, sterically inhibiting the Ub-Tsg101 interaction. By way of example, and not limitation, a prazole compound according to this invention can take on the follow core structure:



Where L is optionally present and is a C_1-C_6 alkyl group, a C_1-C_6 alkoxy group, a -$(CH_2CH_2O)_n$- group where n is an integer from 1 to 6, a phenyl group, or a benzyl group, each of which is optionally substituted. B is a substituted or unsubstituted aromatic or heteroaromatic substituent, and where

X_1 is S(=O) or S;

Y_1 is N or CR_4; and

each of R_1-R_7 is independently selected from hydrogen, C_1-C_6 alkyl, C_1-C_6 alkoxy, perfluoro C_1-C_6 alkyl, perfluoro C_1-C_6 alkoxy, halo, -CN, -OH, -$COOR_8$, substituted or unsubstituted aromatic, or substituted or unsubstituted heteroaromatic, and

each R_8 independently is hydrogen, C_1-C_6 alkyl, phenyl, or benzyl.

Potential Commercial Applications:

- antivirals
- therapeutics
- ESCRT complex formation
- prazole
- antifungal

Development Stage:

- Early stage

Inventors: Nico Tjandra (NHLBI), Carol Carter (Stonybrook), Rolf E. Swenson (NHLBI), David Nyenhuis (NHLBI), Natarajan Raju (NHLBI), Chandra Mushti, (NHLBI), and Venkata Sabbasani (NHLBI).

Intellectual Property: HHS Reference No. E–239–2023–0; U.S. Provisional Patent Application No. 63/545,080 filed October 20, 2023.

Publication: D. A. Nyenhuis, S. Watanabe, R. Bernstein, R. E. Swenson, N. Raju, V. R. Sabbasani, C. Mushti, D.-Y. Lee, C. Carter, N. Tjandra, ''Structural Relationships to Efficacy for Prazole-Derived Antivirals.'' *Adv. Sci.* 2024, 2308312. *https://doi.org/10.1002/advs.202308312.*

Licensing Contact: Michael Shmilovich, Esq, MS, CLP; 301–435–5019; *michael.shmilovich@nih.gov.*

Dated: April 2, 2024.

Michael A. Shmilovich,

Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.

[FR Doc. 2024–07278 Filed 4–4–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2024–0188]

National Boating Safety Advisory Committee; Vacancy; Correction

AGENCY: U.S. Coast Guard, Department of Homeland Security.

ACTION: Notice; request for applications; correction.

SUMMARY: The Coast Guard published a notice on April 1, 2024, regarding a vacancy on the National Boating Safety Advisory Committee (Committee). This Committee advises the Secretary of Homeland Security, via the Commandant of the U.S. Coast Guard, on matters relating to national recreational boating safety. The April 1 notice contained typographical errors that listed multiple vacancies rather than one vacancy. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas Guess, Alternate Designated Federal Officer of the National Boating Safety Advisory Committee; telephone 206–815–0221 or email at *NBSAC@uscg.mil.*

Correction

In the **Federal Register** of April 1, 2024, in FR Doc. 2024–06797, on page 22416, in the second column, correct the first sentence of the Summary to read: ''The U.S. Coast Guard is accepting applications to fill one vacancy on the National Boating Safety Advisory Committee (Committee).''

On page 22417, in the first column, correct the first full paragraph to read: ''In this solicitation for Committee members, we will consider applications for one position as a member representing national recreational boating organizations.''

On page 22417, in the first column, correct the third full paragraph to read: ''The member who will fill the position will be appointed as a representative to represent the position described above and is not a Special Government Employee as defined in 18 U.S.C. 202(a).''

On page 22417, in the first column, correct the first sentence of the Privacy Act Statement to read: ''*Purpose:* To obtain qualified applicants to fill one vacancy on the National Boating Safety Advisory Committee.''

Dated: April 2, 2024.

Michael T. Cunningham,

Chief, Office of Regulations and Administrative Law.

[FR Doc. 2024–07259 Filed 4–4–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Republic of Korea Steel Imports Approved for the Electronic Certification System (eCERT)

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: This document announces that the export certification requirement for imports of steel products of the Republic of Korea that are subject to an absolute quota will be collected through the Electronic Certification System (eCERT). As a result, all imports of steel of the Republic of Korea that are subject to an absolute quota must have a valid export certificate with a corresponding eCERT transmission at the time of entry for consumption or withdrawal from warehouse for consumption. The transition to eCERT will not change the quota filing process or requirements.

DATES: The use of the eCERT process for Korean steel importations that are subject to an absolute quota will be required for steel entered, or withdrawn from a warehouse, for consumption on or after April 22, 2024. CBP will automatically reject filings without correct eCERT information starting May 20, 2024.

FOR FURTHER INFORMATION CONTACT: Julia Peterson, Chief, Quota and Agriculture Branch, Trade Policy and Programs, Office of Trade, (202) 384–8905, or *HQQUOTA@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

Absolute quotas are established by Presidential proclamations, Executive orders, and legislation. *See* section 132.2(a) of title 19 of the Code of Federal Regulations (19 CFR 132.2(a)). On April 30, 2018, President Donald J. Trump signed Proclamation 9740 (83 FR 20683) imposing, among other things, absolute quota limits [1] on certain steel products of the Republic of Korea, pursuant to U.S. Note 16(e), subchapter III, chapter 99, Harmonized Tariff Schedule of the United States (HTSUS), and subheadings 9903.80.05 through 9903.80.58, HTSUS. Subsequently, on August 29, 2018, President Trump signed Proclamation 9777 (83 FR 45025), wherein clause 7 provides that where a government of a country identified in the superior text to subheadings 9903.80.05 through 9903.80.58, HTSUS, notifies the United States that it has established a mechanism for the certification of exports to the United States of the products covered by the quantitative limitations applicable to those subheadings, U.S. Customs and Border Protection (CBP) may require that importers of these products furnish relevant certification of export information in order to qualify for the treatment set forth in those subheadings. Where CBP adopts such a requirement, it must publish notice of the requirement in the **Federal Register**, along with procedures for the submission of the relevant export certification information. No article that is subject to an export certification requirement may be entered for consumption, or withdrawn from warehouse for consumption, except upon presentation of a valid and properly executed export certification.

The Republic of Korea is a country identified in the superior text to subheadings 9903.80.05 through 9903.80.58, HTSUS. The government of the Republic of Korea has notified the United States that it has established a mechanism for the certification of exports to the United States. On September 18, 2019, CBP published a notice in the **Federal Register** (84 FR 49115), announcing that, on October 18, 2019, CBP would begin requiring official export certificates issued by the Republic of Korea for importation of certain steel products into the United States.[2] Following publication of the **Federal Register** notice, CBP issued a message through the Cargo Systems Messaging Service (CSMS) announcing that filers failing to provide the correct export certificate number would receive a warning message from the Automated Commercial Environment (ACE) until January 1, 2020, at which time ACE would begin to reject entries lacking the correct export certificate number. Subsequent CSMS messages delayed the implementation of ACE rejection until

[1] Absolute quotas strictly limit the quantity of goods that may enter the commerce of the United States for a specific period.

[2] Only exporters may obtain valid and properly executed certificates of exportation, which exporters may apply for online via the Korea Iron and Steel Association (KOSA) website at *http://sq.kosa.or.kr/.* The Republic of Korea has authorized KOSA to issue export certificates. Importers should obtain these certificates of exportation from exporters.

further notice, such that steel imports of the Republic of Korea without an export certificate received warning messages, but were not rejected.[3]

The Electronic Certification System (eCERT) is a system developed by CBP that uses electronic data transmissions of information normally associated with a required export document, such as a license or certificate, to facilitate the administration of quotas and ensure that the proper restraint levels are charged without being exceeded. The Republic of Korea currently submits export certificates to CBP via email, and in the administration of the quota, CBP validates the certificate numbers provided by importers on their entry summaries with the information provided by the Republic of Korea. The Republic of Korea requested to participate in the eCERT process to comply with the United States' absolute quota limits for steel exported from the Republic of Korea for importation into the United States. CBP has coordinated with the Republic of Korea to implement the eCERT process, and now the Republic of Korea is ready to participate in this process by transmitting its export certificates to CBP via eCERT.[4]

Foreign countries participating in eCERT transmit information via a global network service provider, which allows connectivity to CBP's automated electronic system for commercial trade processing, ACE. Specific data elements are transmitted to CBP by the importer of record (IOR), or an authorized customs broker, when filing an entry summary with CBP, and those data elements must match eCERT data from the participating country before the subject importations will be entered or withdrawn for consumption. Importers must provide the participating country with their IOR number in advance of filing an entry, and, in turn, the participating country must submit the IOR number as an additional data element of information within the transmission for eCERT.[5] For entries filed through ACE, additional guidance on the submission of the export certificate information is available in the CBP and Trade Automated Interface Requirements (CATAIR), specifically in the chapter entitled Entry Summary Create/Update, regarding the record entitled Importer's Additional Declaration Detail (*https://www.cbp.gov/document/guidance/ace-catair-entry-summary-createupdate-v88*). If a certificate number is not translated properly, the entry will be rejected.

This document announces that the Republic of Korea will be implementing the eCERT process for transmitting export certificates for steel product entries subject to the absolute quota limitation. The entry summary data elements transmitted to CBP for merchandise that is entered, or withdrawn from warehouse, for consumption on or after April 22, 2024 must match the eCERT transmission of an export certificate from the Republic of Korea for the merchandise to be entered or withdrawn for consumption. CBP will automatically reject filings without correct eCERT information starting May 20, 2024. The transition to eCERT will not change the absolute quota filing process or requirements. Importers will continue to provide the export certificate numbers from the Republic of Korea in the same manner as when currently filing entry summaries with CBP. The format of the export certificate numbers will not change as a result of the transition to eCERT. CBP will reject entry summaries that otherwise comply with the absolute quota limitations when filed without a valid export certificate in eCERT.

AnnMarie R. Highsmith,

Executive Assistant Commissioner, Office of Trade.

[FR Doc. 2024–07230 Filed 4–4–24; 8:45 am]

BILLING CODE 9111–14–P

[3] *See* CSMS #40196360 (October 10, 2019) (initial announcement of the testing period), followed by CSMS #41021976 (December 17, 2019) and CSMS #42445519 (April 21, 2020). Full implementation of the certificate requirement was put on hold, while the United States and the Republic of Korea addressed issues related to the management of the certificates.

[4] An exporter's KOSA number functions as the eCERT number.

[5] 87 FR 52015.

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R6–ES–2014–0048; FXES11140600000–245–FF06E22000]

R-Project Transmission Line, Nebraska; Revised Proposed Habitat Conservation Plan for the American Burying Beetle and Draft Supplemental Environmental Impact Statement; Extension of Public Comment Period

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; extension of public comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce that we are extending the comment period for the public to review the draft revised habitat conservation plan (HCP) and draft supplemental environmental impact statement (draft SEIS) associated with Nebraska Public Power District's application under the Endangered Species Act for a permit associated with incidental take of the American burying beetle (*Nicrophorus americanus*). Comments previously submitted, or provided at public meetings, need not be resubmitted, as they will be fully considered in preparing the final documents.

DATES: *Submitting Comments:* The comment period for the revised HCP and draft SEIS, notice of which published on February 9, 2024 (89 FR 9171*),* is extended by 30 days. Comments submitted online at *https://www.regulations.gov/* must be received by 11:59 p.m. eastern time on May 9, 2024. Hardcopy comments must be received on or before May 9, 2024.

ADDRESSES:

Obtaining Documents: The draft SEIS and revised HCP, as well as any comments and other materials that we receive, will be available for public inspection online in Docket No. FWS–R6–ES–2014–0048 at *https://www.regulations.gov.* For information on accessing an on-demand video recording of the March 7, 2024, virtual public meeting, see *https://www.fws.gov/project/r-project-transmission-line.*

Submitting Comments: You may submit comments by one of the following methods:

- *Online: https://www.regulations.gov.* Follow the instructions for submitting comments to Docket No. FWS–R6–ES–2014–0048.
- *U.S. Mail:* Public Comments Processing, Attn: Docket No. FWS–R6–ES–2014–0048; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W; 5275 Leesburg Pike; Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: Jeff Runge, by phone at (308) 382–6468 or by email at *jeff_runge@fws.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TTD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: On February 9, 2024 (89 FR 9171), we, the U.S. Fish and Wildlife Service (Service), announced the availability for public comment of a draft supplemental environmental impact statement (SEIS) pursuant to the requirements of the

National Environmental Policy Act of 1969, as amended (NEPA; 42 U.S.C. 4321 *et seq.*), to evaluate an application for an incidental take permit (ITP) under section 10(a)(1)(B) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*) The Nebraska Public Power District (NPPD) applied for a 50-year permit associated with incidental take of the American burying beetle (*Nicrophorus americanus;* ABB) during construction, operation, and maintenance of a new transmission line in central Nebraska (known as the R-Project). In support of the application, NPPD submitted a revised HCP, which we also announced for public review. For more information, see *https://www.fws.gov/project/r-project-transmission-line.*

With this notice, we are extending the public comment period on the SEIS and HCP (see **DATES** and **ADDRESSES**). The notice of availability established a 60-day public comment period, ending April 9, 2024. We are extending this comment period until May 9, 2024.

Public Availability of Comments

You may submit your comments and materials by one of the methods listed in **ADDRESSES**. Before including your address, phone number, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—might be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Authority

We provide this notice under section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.22 and 17.32) and NEPA (42 U.S.C. 4321 *et seq.*) and its implementing regulations (40 CFR 1506.6 and 43 CFR 46.305).

Marjorie Nelson,

Assistant Regional Director, Ecological Services, Mountain-Prairie Region.

[FR Doc. 2024–07231 Filed 4–4–24; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2024–0047; FXIA16710900000–245–FF09A30000]

Foreign Endangered Species; Receipt of Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on applications to conduct certain activities with foreign species that are listed as endangered under the Endangered Species Act (ESA). With some exceptions, the ESA prohibits activities with listed species unless Federal authorization is issued that allows such activities. The ESA also requires that we invite public comment before issuing permits for any activity otherwise prohibited by the ESA with respect to any endangered species.

DATES: We must receive comments by May 6, 2024.

ADDRESSES: *Obtaining Documents:* The applications, application supporting materials, and any comments and other materials that we receive will be available for public inspection at *https://www.regulations.gov* in Docket No. FWS–HQ–IA–2024–0047.

Submitting Comments: When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. You may submit comments by one of the following methods:

- *Internet: https://www.regulations.gov.* Search for and submit comments on Docket No. FWS–HQ–IA–2024–0047.
- *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2024–0047; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W; 5275 Leesburg Pike; Falls Church, VA 22041–3803.

For more information, see Public Comment Procedures under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Timothy MacDonald, by phone at 703–358–2185 or via email at *DMAFR@fws.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I comment on submitted applications?

We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

You may submit your comments and materials by one of the methods in **ADDRESSES**. We will not consider comments sent by email or to an address not in **ADDRESSES**. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**).

When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. Provide sufficient information to allow us to authenticate any scientific or commercial data you include. The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) those that include citations to, and analyses of, the applicable laws and regulations.

B. May I review comments submitted by others?

You may view and comment on others' public comments at *https://www.regulations.gov* unless our allowing so would violate the Privacy Act (5 U.S.C. 552a) or Freedom of Information Act (5 U.S.C. 552).

C. Who will see my comments?

If you submit a comment at *https://www.regulations.gov,* your entire comment, including any personal identifying information, will be posted on the website. If you submit a hardcopy comment that includes personal identifying information, such as your address, phone number, or email address, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

II. Background

To help us carry out our conservation responsibilities for affected species, and

in consideration of section 10(c) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), we invite public comments on permit applications before final action is taken. With some exceptions, the ESA prohibits certain activities with listed species unless Federal authorization is issued that allows such activities. Permits issued under section 10(a)(1)(A) of the ESA allow otherwise prohibited activities for scientific purposes or to enhance the propagation or survival of the affected species. Service regulations regarding prohibited activities with endangered species, captive-bred wildlife registrations, and permits for any activity otherwise prohibited by the ESA with respect to any endangered species are available in title 50 of the Code of Federal Regulations in part 17.

III. Permit Applications

We invite comments on the following applications.

Applicant: Erich Jarvis, c/o Rockefeller University, New York, NY; Permit No. PER8605010

The applicant requests a permit to import biological samples of all endangered vertebrate species worldwide for the purposes of scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Sea Turtle Conservancy, Gainesville, FL; Permit No. PER8655195

The applicant requests authorization to renew and amend their multi-use permit to import scientific samples taken from the following wild sea turtles, that would be imported from the government of Bermuda, for scientific research purposes: Green sea turtle (*Chelonia mydas*), hawksbill sea turtle (*Eretmochelys imbricata*), loggerhead sea turtle (*Caretta caretta*), and Kemp's ridley sea turtle (*Lepidochelys kempii*). This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Emory University, Atlanta, GA; Permit No. PER7757383

The applicant requests authorization to import biological samples of wild chimpanzees (*Pan troglodytes*) from the Jane Goodall Institute in Tanzania for the purposes of scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Susanne Meyer, Santa Barbara, CA; Permit No. PER6018870

The applicant requests authorization for a single export of biological samples taken from wild blue whales (*Balaenoptera musculus*), from the University of California at Santa Barbara to the University of Calgary's Department of Comparative Biology and Experimental Medicine, for the purpose of scientific research. This notification is for a single export.

Applicant: Todd Dalton, New Orleans, LA; Permit No. PER9214329

The applicant requests a permit to import one tiger (*Panthera tigris*) pelt and skull, one full-body mount and articulated skeleton of a marbled cat (*Pardofelis marmorata*), one full-body mount and articulated skeleton of a clouded leopard (*Neofelis nebulosa*), one full-body mount and articulated skeleton of a red panda (*Ailurus fulgens*), and one taxidermy of a slow loris (*Nycticebus bengalensis*) into the United States from the United Kingdom for the purpose of enhancing the propagation or survival of the species. This notification is for a single import.

Applicant: Naples Zoo, Naples, FL; Permit No. PER8764801

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species, to enhance the propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Common name	Scientific name
Cheetah	*Acinonyx jubatus.*
Red-collared lemur	*Eulemur collaris.*
Slender-horned gazelle.	*Gazella leptoceros.*
Radiated tortoise	*Geochelone radiata.*
Siamang	*Symphalangus syndactylus.*
Ring-tailed lemur	*Lemur catta.*
Clouded leopard	*Neofelis nebulosa.*
Tiger	*Panthera tigris.*
African lion	*Panthera leo melanochaita.*
Red-ruffed lemur	*Varecia rubra.*
Cotton-top tamarin (marmoset).	*Saguinus oedipus.*

Multiple Trophy Applicants

The following applicants request permits to import sport-hunted trophies of male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancing the propagation or survival of the species.

- Tyler Zirpel, Parkston, SD; Permit No. PER8631906
- Ronald Carter, Bonney Lake, WA; Permit No. PER8710173

IV. Next Steps

After the comment period closes, we will make decisions regarding permit issuance. If we issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**. You may locate the notice announcing the permit issuance by searching *https://www.regulations.gov* for the permit number listed above in this document. For example, to find information about the potential issuance of Permit No. 12345A, you would go to *regulations.gov* and search for ''12345A''.

V. Authority

We issue this notice under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and its implementing regulations.

Timothy MacDonald,

Government Information Specialist, Branch of Permits, Division of Management Authority.

[FR Doc. 2024–07203 Filed 4–4–24; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX24GG009950000]

Notice of Public Meeting of Scientific Earthquake Studies Advisory Committee

AGENCY: Geological Survey, Department of the Interior.

ACTION: Notice of teleconference meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972, the U.S. Geological Survey (USGS) is hereby giving notice that the Scientific Earthquake Studies Advisory Committee (SESAC) will meet as noted below.

DATES: The teleconference meetings will be held on Thursday, May 16, 2024, from 11 a.m. to 1 p.m. and from 2 p.m. to 4 p.m. Eastern Daylight Time (EDT); and on Friday, May 17, 2024, from 11 a.m. to 1 p.m. and from 2 p.m. to 4 p.m. EDT.

FOR FURTHER INFORMATION CONTACT: Dr. Gavin Hayes, USGS, by email at *ghayes@usgs.gov* or by telephone at 303–374–4449. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered

within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The teleconference meeting will be open to the public. The SESAC will review the current activities of the USGS Earthquake Hazards Program (EHP) and discuss future priorities. Agenda topics will include EHP update, administration priorities and interactions, budget opportunities, balance of activities supported by the EHP, external grants, National Earthquake Hazards Reduction Program, National Seismic Hazards Model, ShakeAlert, reports from SESAC subcommittees and preparation for a report to the USGS Director.

Meeting Accessibility/Special Accommodations: Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice at least seven (7) business days prior to the meeting to give the Department of the Interior sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Members of the public wishing to participate in the teleconference meeting should contact Dr. Gavin Hayes by email at *ghayes@usgs.gov* at least three (3) business days prior to the meeting. Teleconference meeting call-in information and any updates to the agenda will be provided via email to registered participants.

Time will be allowed at the public meeting for any individual or organization wishing to make formal oral comments. Depending on the number of people who wish to speak and the time available, the time for individual comments may be limited.

Written comments for the SESAC may be sent electronically in advance of the scheduled meeting to Dr. Gavin Hayes by email at *ghayes@usgs.gov* at least three (3) business days prior to the meeting. Any written comments received will be provided to the SESAC members.

Public Disclosure of Comments: Before including your address, phone number, email address, or other personally identifiable information (PII) in your comment, you should be aware that your entire comment—including your PII—may be made publicly available at any time. While you may ask us in your comment to withhold your PII from public review, we cannot guarantee that we will be able to do so.

Detailed minutes of the meeting will be available for public inspection within 90 days of the meeting.

Authority: 5 U.S.C. ch. 10.

Gary Latzke,

Chief of Staff, U.S. Geological Survey Natural Hazards Mission Area.

[FR Doc. 2024–07275 Filed 4–4–24; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_OR_FRN_MO4500177896]

Notice of Availability of the Draft Resource Management Plan and Environmental Impact Statement for the Cascade-Siskiyou National Monument in Oregon/Washington and California

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended (NEPA), the Federal Land Policy and Management Act of 1976, as amended (FLPMA), Presidential Proclamations No. 7318 (Establishment of the Cascade-Siskiyou National Monument) (June 9, 2000) and No. 9564 (Boundary Enlargement of the Cascade-Siskiyou National Monument) (January 12, 2017), the Bureau of Land Management (BLM) has prepared a Draft Resource Management Plan (RMP) and Draft Environmental Impact Statement (EIS) for the Cascade-Siskiyou National Monument (CSNM), and by this notice is providing information announcing the opening of the comment period on the Draft RMP/EIS and the comment period on the BLM's proposed areas of critical environmental concern (ACECs).

DATES: This notice announces the opening of a 90-day comment period for the Draft RMP/EIS beginning with the date following the Environmental Protection Agency's (EPA's) publication of its Notice of Availability (NOA) of the Draft RMP/EIS in the **Federal Register**. The EPA usually publishes its NOAs on Fridays.

To afford the BLM the opportunity to consider comments in the Proposed RMP/Final EIS, please ensure that the BLM receives your comments prior to the close of the 90-day public comment period or 15 days after the last public meeting, whichever is later.

This notice also announces the opening of a 90-day comment period for proposed ACECs. To afford the BLM the opportunity to consider comments for proposed ACECs, please ensure that the BLM receives your comments prior to the close of the 90-day public comment period or 15 days after the last public meeting, whichever is later.

ADDRESSES: The Draft RMP/EIS is available for review on the BLM ePlanning project website at *https://eplanning.blm.gov/eplanning-ui/project/2023675/510.* Written comments related to the CSNM Draft RMP/EIS may be submitted by any of the following methods:

- *Website: https://eplanning.blm.gov/eplanning-ui/project/2023675/510.*
- *Mail:* ATTN: CSNM RMP Project Manager, BLM Medford District, 3040 Biddle Rd., Medford, OR 97504.

Documents pertinent to this proposal may be examined online at *https://eplanning.blm.gov/eplanning-ui/project/2023675/510* and at the BLM Medford District Office, 3040 Biddle Rd., Medford, OR 97504.

FOR FURTHER INFORMATION CONTACT: Ms. Nikki Haskett, Cascade-Siskiyou National Monument RMP Project Manager; telephone (458) 246–8861, address 3040 Biddle Rd., Medford, OR 97504; email *blm_csnm_rmp@blm.gov.* Contact Ms. Haskett to have your name added to our mailing list. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting Ms. Haskett. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: This document provides notice that the BLM Oregon/Washington and California State Directors have prepared a Draft RMP/EIS, announces the opening of the comment period on the Draft RMP/EIS, and announces the comment period on the BLM's proposed ACECs. The planning area is located in Jackson and Klamath Counties in Oregon and Siskiyou County, California, and encompasses approximately 113,500 acres of BLM-administered lands. While most of the BLM-administered lands are within the BLM Ashland and Klamath Falls Field Offices, approximately 5,000 acres are located within the BLM Redding Field Office.

In response to Proclamation No. 9564, multiple plaintiffs sued the President and BLM, claiming that the Monument expansion violated the 1937 Oregon and California Railroad and Coos Bay Wagon Road Grant Lands Act of 1937 (O&C Act). In 2017, two plaintiffs filed separate suits in the U.S. District Court for the District of Columbia. A third plaintiff filed suit in the District of

Oregon. In September 2019, the District of Oregon upheld the Monument expansion, and the U.S. Court of Appeals for the Ninth Circuit affirmed the District Court in April 2023. In November 2019, the District Court for the District of Columbia found the Monument expansion violated the O&C Act by ''reserving land governed by the O&C Act from sustained yield timber production'' and held Proclamation No. 9564 ''invalid and unenforceable as applied to land subject to the O&C Act.'' The government appealed this decision to the U.S. Court of Appeals for the District of Columbia, which reversed the District Court on July 18, 2023, and upheld the Monument expansion. On March 25, 2024, the U.S. Supreme Court declined petitions for review of these cases.

Purpose and Need for the RMP

The purpose and need serve to frame the identification of issues, alternatives development, and effects analyses. Proclamation 7318 and Proclamation 9564 direct the BLM to ''prepare a management plan for this monument'' for the specific purposes of ''protecting the objects of scientific and historic interest identified in Proclamation 7318 and in Proclamation 9564.''

The RMP's purpose (40 CFR 1502.13) is to provide a management framework, including objectives and management direction, that guides the BLM's management of the decision area to protect and restore the resources, objects, and values for which the area was designated. It also serves to protect and restore the objects of scientific and historic interest identified in Presidential Proclamations Nos. 7318 and 9564 by addressing the following:

- Protecting and restoring the diverse ecosystems that provide habitat for rare and endemic and special status wildlife and plant species.
- Protecting and restoring landscape-scale resilience for the area's critically important natural resources.
- Protecting intact habitats and undisturbed corridors that allow for animal migration and movement.
- Reducing fire risk to CSNM objects and values, as well as within the wildland urban interface.
- Managing discretionary uses to protect CSNM objects and values.

The need for the action is to revise the 2008 CSNM RMP to encompass all BLM-administered lands in the monument under one Record of Decision and RMP that is consistent with the proclamations that established and expanded the CSNM (CSNM RMP Plan Evaluation, April 2022). The BLM's current RMPs for lands in the decision area do not address all the legal mandates related to management of the congressionally designated National Conservation Lands (*i.e.,* Soda Mountain Wilderness; the Jenny Creek and Spring Creek Wild and Scenic Rivers; the Applegate Trail, which is part of the California National Historic Trail; and the Pacific Crest National Scenic Trail) and the lands included in President Obama's enlargement of the monument boundary. In addition, some aspects of the existing RMPs covering the planning area need to be updated to be consistent with current BLM policies.

Alternatives Including the Preferred Alternative

The BLM has analyzed four alternatives in detail, including the no action alternative.

Alternative A, the no action alternative, represents current management from the 2008 Cascade-Siskiyou National Monument Approved RMP, 2016 Southwestern Oregon Approved RMP, and the 1993 Redding Approved RMP. In addition to the existing RMPs, there are several non-discretionary designations established by Congress that apply to lands in the planning area and are not reflected in the current RMPs but are part of the no action alternative.

- In March 2009, Congress designated the now 24,707-acre Soda Mountain Wilderness in the original boundary of the CSNM (Pub. L. 111–11, Section 1405).
- In 2009, Congress authorized the Secretary to accept any grazing lease that is donated by a lessee and to terminate any grazing lease acquired (Pub. L. 111–11, Section 1402(a)(1)(A)–(B)). Congress directed that the Secretary also not issue any new grazing leases on those lands and ensure a permanent end to livestock grazing on those lands (Pub. L. 111–11, Section 1402(a)(1)(C)). Additional provisions were described related to donations of portions of grazing leases and modifications to authorized levels of grazing, as well as identifying the permanent end to livestock grazing in the Agate, Emigrant Creek, and Siskiyou allotments in and near the planning area (Pub. L. 111–11, Section 1402(a)(2)–(3) and (b)).
- In March 2019, Congress designated 17.6 miles of Jenny Creek and 1.1 miles of Spring Creek as scenic rivers under the Wild and Scenic Rivers Act (WSRA) (Pub. L. 116–9). Both streams are primarily in the CSNM but also cross into the decision area for the Southwestern Oregon RMP.

Alternative B emphasizes flexibility in planning-level direction, promotes intensive, active management to protect monument resources, and maximizes the potential for an array of discretionary actions that are compatible with the protection of CSNM objects and values. Alternative B would designate both ACECs and Research Natural Areas (RNAs).

Alternative C emphasizes flexibility in planning-level direction but promotes a moderate level of active management for protection, maintenance, and restoration of CSNM resources, and sets some limitations on management actions and tools available. Alternative C utilizes ACEC designations to protect and restore relevant and important values in the CSNM.

Alternative D would rely primarily on natural ecosystem processes that would allow plant community dynamics to unfold without active intervention. Exceptions include the management of young conifer stands (plantations) that are a product of past timber harvest and thinning around legacy trees and along wildfire evacuation routes. Alternative D would not designate any ACECs or RNAs.

The BLM further considered additional alternatives but dismissed them from detailed analysis as explained in the Draft RMP/EIS. The State Directors have identified Alternative C as the preferred alternative. Alternative C was selected as the preferred alternative because it provides management decisions, including objectives and management direction determined to be most effective at resolving planning issues, protecting monument objects and values, and meeting the purpose and need.

Mitigation

The BLM will identify, analyze, and consider best management practices to mitigate the reasonably foreseeable impacts to resources and monument objects. The Draft EIS analyzes all alternatives and, in accordance with 40 CFR 1502.14(e), will include appropriate mitigation measures (best management practices) not already included in the proposed plan or alternatives. Best management practices may include measures to avoid, minimize, rectify, reduce, or eliminate reasonably foreseeable impacts over time, and may be considered at multiple scales, including the landscape scale.

ACECs

Consistent with land use planning regulations at 43 CFR 1610.7–2(b), the BLM is announcing a comment period on the ACECs proposed for designation, which will be open for 90 days.

Comments may be submitted using any of the methods listed in the **ADDRESSES** section.

The proposed ACECs included in the preferred alternative are:

- Cottonwood Glades—approximately 115 acres. Designation proposed to protect native fish, meadows, complex springs, and fen soils. Identified special management considerations may include restricting cattle from the area and restricting motorized and non-motorized vehicular use.
- Mariposa Lily—approximately 239 acres. Designation proposed to protect rare and exemplary oak savanna with core populations of native species, such as the Bureau Sensitive Species Green's mariposa lily and Detlings microseris. Special management considerations may include restoration of native grass and forb components, removal of the invasive yellow star thistle, prescribed fire, and restrictions on vehicular activity and heavy equipment during fire suppression.

The preferred alternative does not propose to designate the following potential ACECs or RNAs:

- Buck Prairie ACEC.
- Jenny Creek RNA.
- Lost Lake RNA.
- Mariposa Preserve Wildlife Crossing ACEC.
- Moon Prairie ACEC.
- Old Baldy RNA.
- Oregon Gulch RNA.
- Priority Wildlife Connectivity Areas ACEC.
- Scotch Creek RNA.
- Tunnel Creek ACEC.

Schedule for the Decision-Making Process

The BLM will provide additional opportunities for public participation consistent with the NEPA and land use planning processes, including a 30-day public protest period and a 60-day Governor's consistency review on the Proposed RMP. The Proposed RMP/Final EIS is anticipated to be available for public protest in the Fall of 2024 with a Record of Decision and Approved RMP in January 2025.

The BLM will hold a total of four public meetings. One meeting will be held virtually, and three meetings will be conducted in-person: in Klamath Falls, Greensprings, and Medford, Oregon. The dates and locations of these meetings will be announced at least 15 days in advance through local media, social media, newspapers, and the ePlanning website (see **ADDRESSES**).

The BLM will continue to consult with Tribal Nations on a government-to-government basis in accordance with Executive Order 13175, BLM Manual Section 1780, and other Departmental policies. Tribal Nation concerns, including impacts on Indian trust assets and potential impacts to cultural resources, will be given due consideration.

You may submit comments on the Draft RMP/EIS in writing to the BLM at any public meetings or to the BLM using one of the methods listed in the **ADDRESSES** section. To be considered, comments must be received by the end of the 90-day comment period. The ePlanning website (see **ADDRESSES**) includes background information on the CSNM and the planning process.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 40 CFR 1506.6, 40 CFR 1506.10, 43 CFR 1610.2, 43 CFR 1610.7–2)

Barry R. Bushue,

BLM Oregon/Washington State Director.

Gordon R. Toevs,

Acting BLM California State Director.

[FR Doc. 2024–07290 Filed 4–4–24; 8:45 am]

BILLING CODE 4331–24–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_NM_FRN_MO4500177326]

Notice of Availability for the Organ Mountains-Desert Peaks National Monument Draft Environmental Impact Statement and Resource Management Plan

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended (FLPMA), the Bureau of Land Management (BLM) New Mexico State Director is announcing the availability of the Organ Mountains-Desert Peaks National Monument (Monument) Draft Environmental Impact Statement (EIS) and Resource Management Plan (RMP). This notice begins a 90-day public comment period to solicit public comments associated with the Monument RMP land use allocations and resource management goals and objectives, and the environmental analysis developed using best available science to identify potential impacts to objects of scientific and historic interest, as well as natural resources, resource values, and wildlife habitat located on the Monument.

DATES: The BLM is encouraging public involvement and input via comment submissions on the Monument Draft EIS/RMP. The BLM will accept comments through June 4, 2024.

To afford the BLM the opportunity to consider and respond to public comment submission for the Monument Draft EIS/RMP, please ensure your comments are submitted and received prior to the close of the 90-day comment period or 15 days after the last public meeting, whichever is later.

ADDRESSES: The public may submit comments on the Draft EIS/RMP to the BLM by any of the following methods: website: *https://eplanning.blm.gov/eplanning-ui/project/92170/;* email: *blm_nm_lcdo_mail@blm.gov;* or mail: BLM Las Cruces District Office, Attention: Monument Manager, 1800 Marquess Street, Las Cruces, NM 88005.

Documents and information relevant to the Monument planning effort may be examined online at *https://eplanning.blm.gov/eplanning-ui/project/92170/510* or in-person at the BLM Las Cruces District Office address mentioned above.

FOR FURTHER INFORMATION CONTACT: Mr. Patrick Rich, RMP Team Lead; telephone: 405–579–7154; email: *prich@blm.gov.* Monument Manager, telephone: 575–525–4358; address: 1800 Marquess Street, Las Cruces, New Mexico 88005.

Contact Mr. Patrick Rich to add your name to our mailing list. Individuals in the United States who are deaf, deaf-blind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting Mr. Patrick Rich. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: This document provides notice that the BLM New Mexico State Director has prepared a Draft EIS/RMP for the Organ Mountains-Desert Peaks National Monument, announces the beginning of the 90-day public comment period for the Monument Draft EIS/RMP, and seeks public input and comment on the Monument Draft RMP land use

allocations and resource management goals and objectives identified in the four land use management alternatives, as well as the environmental analysis developed in the Draft EIS to identify potential effects associated with the four land use management alternatives developed for the Monument Draft RMP. The Monument planning area is in Doña Ana County, New Mexico, and encompasses approximately 496,591 acres of BLM-managed public land. The Monument's current management is directed by the existing 1993 Mimbres RMP, relevant amendments that apply to this planning area, and interim Monument guidance.

Presidential Proclamation 9131 established the Monument through identification of 496,591-acres of BLM-managed public lands in Doña Ana County, New Mexico, surrounding the City of Las Cruces; and directed the BLM to develop an RMP for the Monument. The Draft RMP provides four management alternatives with associated land use allocations and resource management goals and objectives for the protection and preservation of objects of scientific and historic interest, as well as the conservation of natural resources, resource values, and wildlife habitat located on the Monument.

Purpose and Need

The BLM's purpose for developing the Monument EIS/RMP is to respond to: (1) Presidential Proclamation 9131 (79 FR 30431), signed by President Barack Obama on May 21, 2014, establishing approximately 496,591-acres of Federal lands and interest in lands owned or controlled by the government of the United States as the Monument; and (2) the John D. Dingell, Jr. Conservation, Management, and Recreation Act (Dingell Act; Pub. L. 116–9), enacted on March 12, 2019, designating approximately 239,596-acres falling within the established boundaries of the Monument as wilderness and components of the National Wilderness Preservation System, in accordance with the Wilderness Act of 1964 (16 U.S.C. 1131 *et seq.*). The designated wilderness encompasses 10 BLM-managed public land areas within New Mexico: Aden Lava Flow Wilderness, Broad Canyon Wilderness, Cinder Cone Wilderness, East Potrillo Mountains Wilderness, Mount Riley Wilderness, Organ Mountains Wilderness, Potrillo Mountains Wilderness, Robledo Mountains Wilderness, Sierra De Las Uvas Wilderness, and Whitehorn Wilderness.

The need to develop the Monument EIS/RMP is found in FLPMA, which states the BLM shall ''develop, maintain, and, when appropriate, revise land use plans'' (43 U.S.C. 1712(a)); NEPA of 1969 (Pub. L. 91–190); and the BLM's planning regulations (43 CFR 1610.4–6). The BLM is preparing an EIS to identify and analyze reasonably foreseeable direct, indirect, and cumulative environmental impacts associated with the Monument RMP proposed land use allocations and the resource management goals and objectives.

Alternatives

The BLM developed and analyzed the potential effects of four distinct alternatives, demonstrating a reasonable range of alternatives. These were developed and analyzed by the BLM, as mandated by NEPA. Alternative A is the No Action alternative, which is required by Federal law and utilizes existing land use management allocations and resource management goals and objectives. The No Action alternative serves as a base point of reference from which the three action alternatives may be compared and measured for potential effects, both beneficial and adverse. Three action alternatives (Alternatives B, C, and D) were developed and analyzed for potential effects. Each alternative demonstrates a unique means of achieving the purpose and need through varying land use allocations and resource management goals and objectives. The following is a brief synopsis of the themes used to develop each alternative:

- *Alternative A (No Action):* Maintains the 1993 Mimbres RMP land use allocations and resource management goals and objectives. Incorporates Monument management direction and guidance from Presidential Proclamation 9131 and the 2019 Dingell Act.
- *Alternative B (Protection-focused):* Protects objects of scientific and historic interest. Protects, preserves, and enhances habitat, natural resources, and resource values while providing limited recreation and travel opportunities. Most proactive in promoting land use management activities focused on preservation, restoration, and enhancement.
- *Alternative C (Agency Preferred Alternative):* Preserves objects of scientific and historic interest within the Monument. Provides an objective approach to land use management, employing preservation and conservation principles for habitat management, natural resource management, and resource values. Alternative C employs targeted preservation goals and objectives, while allowing uses that promote sustained socioeconomic progression.
- *Alternative D (Recreation and Use-focused):* Preserves objects of scientific and historic interest within the Monument. Institutes foundational conservation management principles for the management of habitat, natural resources, and resource values, while simultaneously providing an enhanced visitor experience that emphasizes a more diverse array of recreational opportunities. Includes targeted preservation goals and objectives where appropriate and necessary.

The BLM New Mexico State Director has identified Alternative C as the agency preferred alternative. Alternative C was determined to be effective at protecting and preserving Monument objects while balancing resource uses and meeting the purpose and need. The preferred alternative includes important conservation and preservation measures that will protect Monument objects of scientific and historic interest, as well as other resources and resource values, including:

- *Wilderness areas:* Emphasizes preservation of wilderness character, with allowance for compatible uses;
- *Areas of Critical Environmental Concern (ACEC):* Designates two ACECs comprised of 38,085 acres within the Doña Ana Mountains (1,427 acres) and the Organ Mountains (36,658 acres);
- *Special Recreation Management Area (SRMA):* Designates SRMAs comprised of 45,871 acres within the Doña Ana Mountains (5,858 acres) and Organ Mountains (36,658 acres). Recreational focus on camping, equestrian, and pedestrian use;
- *Soils:* provides for protection and active management of soils, while limiting soil disturbing activities;
- *Vegetative communities:* provides for the protection, preservation, and restoration of reference vegetative communities;
- *Wildlife:* preserves and restores native habitat, while enhancing wildlife corridors and connectivity;
- *Visual resources:* preserves high value visual resources through protective management goals and objectives;
- *Livestock grazing:* establishes goals and objectives developed to ensure appropriate preservation and conservation of Monument objects, natural resources, and resource values, and defers to a subsequent site-specific evaluation of compatibility of grazing with the Presidential Proclamation and land health evaluations to make further adjustments to grazing management guidance and decisions;

• *Travel management:* establishes protective goals and objectives by limiting off-highway vehicles to designated roads and mechanized vehicles to designated roads and trails; and

• *Lands and realty:* provides resource preservation and conservation through establishment of right-of-way exclusion and avoidance areas across the Monument.

Public Involvement Process

The date(s) and location(s) of public meeting(s), in-person or virtual, will be announced at least 15 days in advance through local media, social media, and the ePlanning website (*https://eplanning.blm.gov/eplanning-ui/project/92170/510*).

The ePlanning website *https://eplanning.blm.gov/eplanning-ui/project/92170/510* includes information about the Monument, a BLM planning process overview, issues identified for planning, and interim management guidance. The BLM encourages broad public involvement and the submission of substantive comments on: (1) the issues identified for analysis; (2) the land use allocations and resource management goals and objectives associated with the four alternatives; (3) other relevant information; and (4) the environmental analysis conducted in the Monument Draft EIS. However, the public may comment on any aspect of the Monument Draft EIS/RMP.

A substantive comment is one that is based on or uses a rational and/or science-based approach to critique the information, data, or methodology employed to develop the Monument Draft EIS/RMP; the construct of the alternative(s); or the methodology and projected effects derived from the environmental analysis and utilized to develop the Monument Draft EIS. All public comments received during the 90-day public comment period will be accepted, reviewed, and logged into the administrative record. However, substantive comments submitted to the BLM during the 90-day public comment period will be accepted, reviewed, responded to by the BLM, and potentially used for document amendment through incorporation of comment substance.

Responsible Official

The New Mexico State Director is the deciding official for the Monument EIS/RMP and the Record of Decision.

Decision To Be Made

The BLM New Mexico State Director will select from the four alternatives developed and analyzed in the Monument Draft EIS/RMP or a combination of those alternatives, and the specific land use allocations and resource management goals and objectives to be employed for the protection, preservation, restoration, enhancement, conservation, administration, and management of the objects of scientific and historic interest, natural resources, resource values, and wildlife habitat located on Monument lands.

BLM Interdisciplinary Team

The BLM used an interdisciplinary approach to develop the Monument Draft EIS/RMP through careful consideration of the issues and concerns identified. Specialists with expertise in the following disciplines were involved in the development and analysis of the Monument Draft EIS/RMP: botany/vegetation; lands and realty; renewable energy; fire ecology and management; wilderness characteristics; wildlife and special status species; public health and safety; geology and minerals; paleontology; air resources; climate change; water resources; recreation; transportation; visual resources; rangeland management; cultural resources; Tribal resources; soils; sociology; and economics.

Additional Information: The BLM interdisciplinary team identified, analyzed, and considered mitigation to address reasonably foreseeable impacts associated with land use allocations and resource management goals and objectives employed to develop the alternatives, in accordance with 40 CFR 1502.14(e). The BLM interdisciplinary team included appropriate mitigation measures in the proposed alternatives. Mitigation includes avoidance, minimization, rectification, reduction, or elimination over time, and compensation and was considered at multiple planning scales, including the landscape level.

The BLM interdisciplinary team proactively coordinated the NEPA and land use planning processes early in the planning effort to ensure compliance with applicable procedural requirements under the Endangered Species Act (16 U.S.C. 1536) and Section 106 of the National Historic Preservation Act (54 U.S.C. 306108), as provided in 36 CFR 800.2(d)(3), including public involvement requirements of Section 106. Information concerning historic and cultural resources and threatened and endangered species within the area potentially affected by the draft plan assisted the BLM interdisciplinary team in identifying and evaluating potential impacts to those resources.

The BLM engaged in consultation with thirteen federally recognized Tribes on a government-to-government basis in accordance with Executive Order 13175, BLM Manual section 1780, and other Departmental policies. Tribal concerns, including potential impacts to Indian trust assets and cultural resources, were given due consideration. Federal, State, and local agencies, along with Indian Tribal Nations and other stakeholders that demonstrated interest in or could have been impacted by the Monument RMP, were invited to participate in the scoping process and, if eligible, were invited to participate as a cooperating agency. The BLM intends to continue government-to-government consultation meetings and will continue to solicit input and develop opportunities for meaningful consultation with potentially affected Tribal Nations throughout the land use planning process.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 40 CFR 1501.9 and 43 CFR 1610.2)

Melanie G. Barnes,

BLM New Mexico State Director.

[FR Doc. 2024–07106 Filed 4–4–24; 8:45 am]

BILLING CODE 4331–23–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MO4500178485]

Notice of Public Meeting, Southern New Mexico Resource Advisory Council, New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976, as amended, and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management's (BLM) Southern New Mexico Resource Advisory Council (RAC) will meet as indicated below.

DATES: The RAC is scheduled to host an in-person meeting, with a virtual participation option, on Thursday, June 6, 2024, from 8 a.m. to 4 p.m. Mountain Time (MT) at the BLM Las Cruces District Office. All RAC meetings are open to the public.

ADDRESSES: BLM Las Cruces Office, 1800 Marquess Street, Las Cruces, New Mexico 88005. A virtual participation option is available on the Zoom Webinar platform. To register, go to *https://blm.zoomgov.com/webinar/register/WN_LsAFuJWfSMKLCv1hux6kUA.*

FOR FURTHER INFORMATION CONTACT: Wendy Brown, BLM Pecos District Office, 2909 West Second Street, Roswell, New Mexico 880102; 575–627–0259; *wabrown@blm.gov.* Individuals in the United States who are deaf, blind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States can use relay services offered within their respective country to make international calls to the accessibility point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The chartered 12-member Southern New Mexico RAC advises the Secretary of the Interior, through the BLM New Mexico State Director, about planning and management of public land resources located within the jurisdictional boundaries of the RAC.

Planned meeting agenda items include a discussion and a vote on recreation fee increases for the BLM's Three Rivers Petroglyphs Recreation Site, a briefing on a recreation fee increase for Datil Well Campground, a discussion of land access issues in Southern New Mexico, updates from the BLM Socorro Field Office and the Pecos and Las Cruces District Offices, and other issues that may arise. A final agenda will be posted two weeks in advance of the meeting on the RAC web page at *www.blm.gov/get-involved/resource-advisory-council/near-you/new-mexico/southern-rac.*

Public Comment Procedures: The BLM welcomes comments from all interested parties. There will be a half-hour public comment period during the June 6 meeting beginning at 1:30 p.m. MT for any interested members of the public who wish to address the Southern New Mexico RAC. Advanced written comments pertaining to this meeting may be submitted in advance to the individual listed in the **FOR FURTHER INFORMATION** section of this notice. Please include ''RAC Comment'' in your submission. Depending on the number of persons wishing to speak, the time for individual comments may be limited. Before including an address, phone number, email address, or other personal identifying information in any comment, please be aware that all comments—including personal identifying information—may be made publicly available at any time. While requests can be made to withhold personal identifying information from public review, BLM cannot guarantee it will be able to do so.

Meeting Accessibility/Special Accommodations: For sign language interpreter services, assistive listening devices, or other reasonable accommodations, please contact Wendy Brown, BLM Pecos District Office, at (575) 627–0259, or *wabrown@blm.gov* at least seven business days before the meeting to ensure there is sufficient time to process the request. The Department of the Interior manages accommodation requests on a case-by-case basis.

Detailed meeting minutes for the Southern New Mexico RAC are maintained in the Las Cruces District Office, located at 1800 Marquess Street, Las Cruces, New Mexico 88005. Meeting minutes will be available for public inspection and reproduction during regular business hours within 90 days following the meeting. Minutes will also be posted on the RAC web page at *https://www.blm.gov/get-involved/resource-advisory-council/near-you/new-mexico/southern-rac.*

Authority: 43 CFR 1784.4–1.

James Stovall,

BLM Pecos District Manager.

[FR Doc. 2024–07283 Filed 4–4–24; 8:45 am]

BILLING CODE 4331–24–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–579–580 and 731–TA–1369–1372 (Review)]

Fine Denier Polyester Staple Fiber From China, India, South Korea, and Taiwan

Determinations

On the basis of the record [1] developed in the subject five-year reviews, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the countervailing duty orders on fine denier polyester staple fiber (''fine denier PSF'') from China and India and the antidumping duty orders on fine denier PSF from China, India, South Korea, and Taiwan would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted these reviews on February 1, 2023 (88 FR 6790) and determined on May 8, 2023 that it would conduct full reviews (88 FR 31006, May 15, 2023). Notice of the scheduling of the Commission's reviews and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on August 30, 2023 (88 FR 59940). The Commission conducted its hearing on January 23, 2023. All persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on April 1, 2024. The views of the Commission are contained in USITC Publication 5500 (April 2024), entitled *Fine Denier Polyester Staple Fiber from China, India, South Korea, and Taiwan (Inv. Nos. 701–TA–579–580 and 731–TA–1369–1372 (Review).*

By order of the Commission.

Issued: April 1, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–07212 Filed 4–4–24; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1203 (Second Review)]

Xanthan Gum From China; Determination

On the basis of the record [1] developed in the subject five-year review, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the antidumping duty order on xanthan gum from China would be likely to lead to continuation or recurrence of material injury to an industry in the United

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

States within a reasonably foreseeable time.

Background

The Commission instituted this review on October 2, 2023 (88 FR 67809) and determined on January 5, 2024 that it would conduct an expedited review (89 FR 3427, January 18, 2024).

The Commission made this determination pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determination in this review on April 1, 2024. The views of the Commission are contained in USITC Publication 5501 (April 2024), entitled *Xanthan Gum from China: Investigation No. 731–TA–1203 (Second Review).*

By order of the Commission.

Issued: April 1, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–07214 Filed 4–4–24; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint *Certain Cameras, Camera Systems, and Accessories Used Therewith, DN 3736;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of GoPro, Inc. on March 29, 2024. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain cameras, camera systems, and accessories used therewith. The complaint names as respondents: Arashi Vision Inc. d/b/a Insta360 of China; and Arashi Vision (U.S.) LLC d/b/a Insta360 of Irvine, CA. The complainant requests that the Commission issue a general exclusion order or, in the alternative, limited exclusion orders and cease and desist orders, and impose a bond upon respondent alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due, notwithstanding § 201.14(a) of the Commission's Rules of Practice and Procedure. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3736'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]).

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: April 1, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–07215 Filed 4–4–24; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 23–64]

Traesa A. Brown, M.D.; Decision and Order

On August 31, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Traesa A. Brown, M.D. (Respondent) of Florence, South Carolina. OSC, at 1, 5. The OSC/ISO informed Respondent of the immediate suspension of her DEA Certificate of Registration (registration or COR), Control No. BB9937624, pursuant to 21 U.S.C. 824(d), alleging that Respondent's continued registration constitutes '' 'an imminent danger to the public health or safety.' '' *Id.* at 1 (quoting 21 U.S.C. 824(d)). The OSC/ISO also proposed the revocation of Respondent's registration, alleging that Respondent's continued registration is inconsistent with the public interest and alleging that Respondent has no state authority to handle controlled substances. *Id.* (citing 21 U.S.C. 823(g)(1), 824(a)(3), 824(a)(4)).

On September 20, 2023, Respondent requested a hearing. On October 13, 2023, the Government filed a Motion for Summary Disposition only pertaining to the allegation that Respondent lacks state authority to handle controlled substances.[1] *See* Government's Notice of Filing of Evidence and Motion for Summary Disposition (Motion for Summary Disposition), dated October 13, 2023.[2] Respondent did not respond to the Government's Motion for Summary Disposition. On October 23, 2023, Administrative Law Judge Paul E. Soeffing (the ALJ) granted the Government's Motion for Summary Disposition and recommended the revocation of Respondent's registration, finding that because Respondent lacks state authority to handle controlled substances in South Carolina, the state in which she is registered with DEA, ''there is no other fact of consequence for this tribunal to decide in order to determine whether or not she is entitled to hold a COR.'' Order Granting the Government's Motion for Summary Disposition, and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (RD), at 6. Respondent did not file exceptions to the RD.

Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the entirety of the ALJ's rulings, findings of fact, conclusions of law, and recommended sanction as found in the RD and summarizes and expands upon portions thereof herein.

Findings of Fact

The Government asserts that on October 1, 2022, Respondent's South Carolina controlled substance registration expired. RD, at 3–4.[3] Further, the Government asserts that on June 30, 2023, Respondent's South Carolina medical license expired. RD, at 4.[4]

According to South Carolina online records, of which the Agency takes official notice, Respondent's South Carolina controlled substance registration is expired.[5] SC DHEC Bureau of Drug Control, Controlled Substances Registration Verification, *https://.dhec.sc.gov//Licensing/Home/Verify* (last visited date of signature of this Order). Further, Respondent's South Carolina medical license is listed as ''lapsed.'' South Carolina Board of Medical Examiners, Licensee Lookup, *https://verify.llronline.com/LicLookup/Med/Med.aspx* (last visited date of signature of this Order).

Accordingly, the Agency finds that Respondent is not currently licensed to engage in the practice of medicine nor to handle controlled substances in South Carolina, the state in which she is registered with the DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (CSA) ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71371, 71372 (2011), *pet. for rev. denied,* 481

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

[1] This suggests that the Government has dropped the public interest allegation included in the OSC/ISO; as such, the Agency will only consider the lack of state authority allegation from the OSC/ISO.

[2] The Government originally filed a Motion for Summary Disposition on October 12, 2023, and therein asserted that Respondent had failed to timely file an Answer to the allegations in the OSC/ISO. RD, at 2 n.4; Motion for Summary Disposition, dated October 12, 2023, at 3–4. Later on October 12, 2023, the Government was informed that Respondent had filed an Answer on October 10, 2023, and was provided with a copy of Respondent's Answer. RD, at 2 n.4. On October 13, 2023, the Government filed its amended Motion for Summary Disposition, referenced in this Decision, with revisions based on its receipt of the copy of Respondent's Answer. *Id.; see also* Motion for Summary Disposition, dated October 13, 2023.

[3] *See also* Motion for Summary Disposition, dated October 13, 2023, Exhibit (GX) 1; Motion for Summary Disposition, dated October 13, 2023, at 4–5.

[4] *See also* Motion for Summary Disposition, dated October 13, 2023, at 4. As noted by the ALJ, the Government did not submit documentary evidence regarding the status of Respondent's South Carolina medical license as they had for Respondent's South Carolina controlled substance registration, *see supra* n.3. RD, at 4 n.8.

[5] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Respondent may dispute the Agency's finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.gov.*

F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27616, 27617 (1978).[6]

According to South Carolina statute, ''[e]very person who manufactures, distributes, or dispenses any controlled substance or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance, shall obtain a registration issued by the [Department of Health and Environmental Control] in accordance with its rules and regulations.'' S.C. Code section 44–53–290(a) (2024). Further, ''dispense'' means ''to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for the delivery.'' *Id.* section 44–53–110(15).

Here, the undisputed evidence in the record is that Respondent currently lacks authority to dispense controlled substances in South Carolina because her South Carolina controlled substance registration is expired. As discussed above, an individual must hold a controlled substance registration to dispense a controlled substance in South Carolina. Thus, because Respondent lacks authority to handle controlled substances in South Carolina, Respondent is not eligible to maintain a DEA registration. RD, at 6. Accordingly, the Agency will order that Respondent's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BB9937624 issued to Traesa A. Brown, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Traesa A. Brown, M.D., to renew or modify this registration, as well as any other pending application of Traesa A. Brown, M.D., for additional registration in South Carolina. This Order is effective May 6, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on April 1, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2024–07237 Filed 4–4–24; 8:45 am]

BILLING CODE 4410–09–P

[6] This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(g)(1) (this section, formerly § 823(f), was redesignated as part of the Medical Marijuana and Cannabidiol Research Expansion Act, Pub. L. 117–215, 136 Stat. 2257 (2022)). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR at 71371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51104, 51105 (1993); *Bobby Watts, M.D.,* 53 FR 11919, 11920 (1988); *Frederick Marsh Blanton,* 43 FR at 27,617.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 23–63]

Ralph Reach, M.D.; Decision And Order

On August 30, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Ralph Reach, M.D. (Respondent). OSC, at 1, 4. The OSC proposed the revocation of Respondent's DEA Certificates of Registration Nos. FR0673548 and FR0004589 at the registered addresses of 142 Mall Church Road, Cedar Bluff, Virginia 24609 and 102 North Broadway Street, Johnson City, Tennessee 37601, respectively. *Id.* at 1. The OSC alleged that Respondent's DEA registrations should be revoked because Respondent is ''without authority to prescribe, administer, dispense, or otherwise handle controlled substances in the State of Tennessee and the Commonwealth of Virginia, the jurisdictions in which [he is] registered with DEA.'' *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

On September 14, 2023, Respondent requested a hearing. On September 27, 2023, the Government filed a Motion for Summary Disposition, which Respondent opposed. On November 7, 2023, Administrative Law Judge Teresa A. Wallbaum (the ALJ) granted the Government's Motion for Summary Disposition and recommended the revocation of Respondent's registration, finding that because Respondent lacks state authority to handle controlled substances in Tennessee and Virginia, the states in which he is registered with DEA, ''[t]here is no genuine issue of material fact in this case.'' Order Granting the Government's Motion for Summary Disposition, and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (RD), at 7. On November 9, 2023, Respondent filed a document titled ''Notice of Appeal'' [1] in response to the RD.

Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the entirety of the ALJ's rulings, findings of fact, conclusions of law, and recommended sanction as found in the RD and summarizes and expands upon portions thereof herein.

Findings of Fact

Effective June 30, 2023, the Tennessee Department of Health revoked Respondent's Tennessee medical license. RD, at 5.[2] Further, effective July 6, 2023, the Virginia Department of Health Professions suspended Respondent's Virginia medical license. *Id.*[3]

According to Tennessee and Virginia online records, of which the Agency takes official notice, Respondent's Tennessee medical license remains revoked and Respondent's Virginia medical license remains suspended.[4]

[1] The document blankly asserts that that Respondent appeals the RD without explaining the basis therefor or otherwise identifying his exceptions to the RD pursuant to 21 CFR 1316.66. *See* Respondent's Notice of Appeal.

[2] *See also* Government's Notice of Filing of Evidence and Motion for Summary Disposition, Exhibit (GX) 3, at 1.

[3] *See also* GX 1, at 1–2.

[4] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Respondent may dispute the Agency's finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by

Tennessee Department of Health License Verification, *https://apps.health.tn.gov/Licensure/* default.aspx (last visited date of signature of this Order); Virginia Department of Health Professions License Lookup, *https://dhp.virginiainteractive.org/*lookup (last visited date of signature of this Order).

Accordingly, the Agency finds that Respondent is not currently licensed to practice medicine in either Tennessee or Virginia, the states in which he is registered with the DEA.[5]

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (CSA) ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition[6] for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71371, 71372 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27616, 27617 (1978).[7]

According to Tennessee statute, ''dispense'' means ''to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery''; a ''practitioner'' means a ''physician . . . or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in [the] state.'' Tenn. Code Ann. § 39–17–402(7), (23)(A) (West 2024). Similarly, under Virginia statute, ''dispense'' means ''to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery''; a ''practitioner'' means a ''physician . . . or other person licensed, registered, or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to a controlled substance in the course of professional practice or research in the [state].'' Va. Code Ann. § 54.1–3401 (West 2023).

Here, the undisputed evidence in the record is that Respondent lacks authority to practice medicine in both Tennessee and Virginia. As discussed above, in both Tennessee and Virginia, a physician must be a licensed practitioner to dispense a controlled substance. Thus, because Respondent lacks authority to practice medicine in both Tennessee and Virginia and, therefore is not authorized to handle controlled substances in either Tennessee or Virginia, Respondent is not eligible to maintain a DEA registration in those states. RD, at 6–7. Accordingly, the Agency will order the Respondent's DEA registrations be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificates of Registration Nos. FR0673548 and FR0004589 issued to Ralph Reach, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Ralph Reach, M.D., to renew or modify these registrations, as well as any other pending application of Ralph Reach, M.D., for additional registration in Tennessee or Virginia. This Order is effective May 6, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on April 1, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2024–07236 Filed 4–4–24; 8:45 am]

BILLING CODE 4410–09–P

email to the other party and to Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.gov.*

[5] Because Respondent's DEA registrations at issue here are based on his Tennessee and Virginia medical licenses, which have undeniably been revoked and suspended, it is of no consequence that he may maintain a valid medical license and separate DEA registration based in North Carolina, *see* Respondent's Opposition, at 4. RD, at 7; *Omar Garcia, M.D.,* 87 FR 32186, 32187 n.6 (2022).

[6] As such, the Agency finds Respondent's arguments regarding the discretionary nature of 21 U.S.C. 824(a)(3), *see* Respondent's Response in Opposition to Government's Motion for Summary Disposition (Respondent's Opposition), at 4, to be unavailing. RD, at 6; *see also Bhanoo Sharma, M.D.,* 87 FR 41355, 41356 n.4 (2022).

[7] This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(g)(1) (this section, formerly § 823(f), was redesignated as part of the Medical Marijuana and Cannabidiol Research Expansion Act, Pub. L. 117–215, 136 Stat. 2257 (2022)). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR at 71371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51104, 51105 (1993); *Bobby Watts, M.D.,* 53 FR 11919, 11920 (1988); *Frederick Marsh Blanton,* 43 FR at 27617. Moreover, because ''the controlling question'' in a proceeding brought under 21 U.S.C. 824(a)(3) is whether the holder of a practitioner's registration ''is currently authorized to handle controlled substances in the [S]tate,'' Hooper, 76 FR at 71371 (quoting *Anne Lazar Thorn,* 62 FR 12847, 12848 (1997)), the Agency has also long held that revocation is warranted even where a practitioner is still challenging the underlying action. *Bourne Pharmacy,* 72 FR 18273, 18274 (2007); *Wingfield Drugs,* 52 FR 27070, 27071 (1987). Thus, it is of no consequence that Respondent is still challenging the underlying action here, *see* Respondent's Opposition, at 4. RD, at 6–7. What is consequential is the Agency's finding that Respondent is not currently authorized to dispense controlled substances in either Tennessee or Virginia, the states in which he is registered with the DEA. *Adley Dasilva, P.A.,* 87 FR 69341, 69341 n.2 (2022).

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act

On April 1, 2024, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Western District of New York in the lawsuit entitled *U.S.* v. *Kyocera AVX Components Corporation,* Civil No. 1:24–cv–305.

In this action, the United States seeks, pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA''), 42 U.S.C. 9601, *et seq.,* injunctive relief and recovery of response costs regarding the Olean Wellfield Superfund Site in the City of Olean, the Town of Olean, and the Town of Portville, New York (the ''Site''). The proposed Consent Decree will require the Kyocera AVX Components Corporation (''KAVX'') to perform the ''Operable Unit 5'' (''OU5'') remedial action at the Site, and to reimburse the U.S. Environmental Protection Agency for its past and future costs regarding the OU5 remedial action. The OU5 remedial action comprises the performance of a soil cleanup at a parcel of property owned by KAVX.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *U.S.* v. *Kyocera AVX Components Corporation,* D.J. Ref. No. 90–11–3–181/2. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Any comments submitted in writing may be filed in whole or in part on the public court docket without notice to the commenter.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* If you require assistance accessing the Consent Decree, you may request assistance by email or by mail to the addresses provided above for submitting comments.

Henry Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2024–07269 Filed 4–4–24; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Veterans' Employment and Training Service

Advisory Committee on Veterans' Employment, Training and Employer Outreach (ACVETEO): Meeting

AGENCY: Veterans' Employment and Training Service (VETS), Department of Labor (DOL).

ACTION: Notice of open meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the ACVETEO. The ACVETEO will discuss the DOL core programs and services that assist veterans seeking employment and raise employer awareness as to the advantages of hiring veterans. There will be an opportunity for individuals or organizations to address the committee. Any individual or organization that wishes to do so should contact Mr. Gregory Green at *ACVETEO@dol.gov.* Additional information regarding the Committee, including its charter, current membership list, annual reports, meeting minutes, and meeting updates may be found at *https://www.dol.gov/agencies/vets/about/advisorycommittee.* This notice also describes the functions of the ACVETEO. This document is intended to notify the general public.

DATES: Tuesday, April 23, 2024 beginning at 9 a.m. and ending at approximately 12 p.m. (EDT).

ADDRESSES: This ACVETEO meeting will be held via TEAMS and teleconference. Meeting information will be posted at the link below under the Meeting Updates tab. *https://www.dol.gov/agencies/vets/about/advisorycommittee.*

Notice of Intent to Attend the Meeting: All meeting participants should submit a notice of intent to attend by Friday, April 19, 2024, via email to Mr. Gregory Green at *ACVETEO@dol.gov,* subject line ''April 2024 ACVETEO Meeting.'' Individuals who will need accommodations for a disability in order to attend the meeting (*e.g.,* interpreting services, assistive listening devices, and/or materials in alternative format) should notify the Advisory Committee no later than Friday, April 19, 2024, by contacting Mr. Gregory Green at *ACVETEO@dol.gov.*

Requests made after this date will be reviewed, but availability of the requested accommodations cannot be guaranteed.

FOR FURTHER INFORMATION CONTACT: Mr. Gregory Green, Designated Federal Official for the ACVETEO, *ACVETEO@dol.gov,* (202) 693–4734.

SUPPLEMENTARY INFORMATION: The ACVETEO is a Congressionally mandated advisory committee authorized under title 38, U.S. Code, section 4110 and subject to the Federal Advisory Committee Act, 5 U.S.C. 10. The ACVETEO is responsible for: assessing employment and training needs of veterans; determining the extent to which the programs and activities of the U.S. Department of Labor meet these needs; assisting to conduct outreach to employers seeking to hire veterans; making recommendations to the Secretary, through the Assistant Secretary for Veterans' Employment and Training Service, with respect to outreach activities and employment and training needs of veterans; and carrying out such other activities necessary to make required reports and recommendations. The ACVETEO meets at least quarterly.

Agenda

9:00 a.m. Welcome and remarks, James D. Rodriguez, Assistant Secretary, Veterans' Employment and Training Service
9:05 a.m. Administrative Business, Gregory Green, Designated Federal Official
9:15 a.m. Briefing on Apprenticeships
9:45 a.m. Briefing on Partnerships
10:15 a.m. Break
10:30 a.m. Briefing on Grants
11:00 a.m. Briefing on Military Spouse/USERRA
11:30 a.m. Public Forum, Gregory Green, Designated Federal Official
12:00 p.m. Adjourn

Signed in Washington, DC, this 1st day of April 2024.

James D. Rodriguez,

Assistant Secretary, Veterans' Employment and Training Service.

[FR Doc. 2024–07206 Filed 4–4–24; 8:45 am]

BILLING CODE 4510–79–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: 024–028]

NASA Advisory Council; STEM Engagement Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the National Aeronautics and Space Administration announces a meeting of the Science, Technology, Engineering and Mathematics (STEM) Engagement Committee of the NASA

Advisory Council (NAC). This Committee reports to the NAC.

DATES: Thursday, May 2, 2024, 10 a.m. to 4 p.m., eastern time.

ADDRESSES: Virtual meeting by dial-in teleconference and WebEx only.

FOR FURTHER INFORMATION CONTACT: Dr. Tara Strang, Designated Federal Officer (DFO), NAC STEM Engagement Committee, NASA Headquarters, Washington, DC 20546, (216) 410–4335, or *tara.m.strang@nasa.gov.*

SUPPLEMENTARY INFORMATION: This meeting will be available virtually telephonically and by WebEx. You must use a touch-tone phone to participate in this meeting. Any interested person may dial the toll free access number 415–527–5035, and then the access code: 282 927 39898 followed by the # sign. To join via WebEx, use link: *https://nasaenterprise.webex.com/nasaenterprise/j.php?MTID=m9fa1e7b4c5aec757b120371acdecef7e* and the meeting number is 2829 273 9898 and the password is kZ5xXCda3@3 (Password is case sensitive.) NOTE: If dialing in, please ''mute'' your telephone. The agenda for the meeting will include the following:

—Opening Remarks by Chair

—NASA STEM Engagement Update

—Presentation Topics:

- NASA STEM Engagement Partnerships
- NASA OSTEM and ARMD Collaborations
- NASA STEM Impacts

—Formulation of New Findings and Recommendations

—Other Related Topics

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Carol J. Hamilton,

Acting Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2024–07285 Filed 4–4–24; 8:45 am]

BILLING CODE P

NATIONAL SCIENCE FOUNDATION

Request for Recommendations for Membership on Directorate and Office Advisory Committees

ACTION: Notice.

SUMMARY: The National Science Foundation (NSF) requests recommendations for membership on its scientific and technical Federal advisory committees. Recommendations should consist of the name of the submitting individual, the organization or the affiliation providing the member nomination, the name of the recommended individual, the recommended individual's curriculum vita, an expression of the individual's interest in serving, and the following recommended individual's contact information: employment address, telephone number, fax number, and email address. Self-recommendations are accepted. If you would like to make a membership recommendation for any of the NSF scientific and technical Federal advisory committees, please send your recommendation to the appropriate committee contact person listed in the chart below.

ADDRESSES: The mailing address for the National Science Foundation is 2415 Eisenhower Avenue, Alexandria, VA 22314.

Web links to individual committee information may be found on the NSF website: NSF Advisory Committees.

SUPPLEMENTARY INFORMATION: Each Directorate and Office has an external advisory committee that typically meets twice a year to review and provide advice on program management; discuss current issues; and review and provide advice on the impact of policies, programs, and activities in the disciplines and fields encompassed by the Directorate or Office. In addition to Directorate and Office advisory committees, NSF has several committees that provide advice and recommendations on specific topics including astronomy and astrophysics; environmental research and education; equal opportunities in science and engineering; cyberinfrastructure; international science and engineering; and business and operations.

A primary consideration when formulating committee membership is recognized knowledge, expertise, or demonstrated ability.[1] Other factors that may be considered are balance among diverse institutions, regions, and groups underrepresented in science, technology, engineering, and mathematics. Committee members serve for varying term lengths, depending on the nature of the individual committee. Although we welcome the recommendations we receive, we regret that NSF will not be able to acknowledge or respond positively to each person who contacts NSF or has been recommended. NSF intends to publish a similar notice to this on an annual basis. NSF will keep recommendations active for 12 months from the date of receipt.

The chart below is a listing of the committees seeking recommendations for membership. Recommendations should be sent to the contact person identified below. The chart contains web addresses where additional information about individual committees is available.

Advisory committee	Contact person
Advisory Committee for Biological Sciences, *https://www.nsf.gov/bio/advisory.jsp*.	Lynette Bouchie, Directorate for Biological Sciences; phone: (703) 292–8400; email: *lbouchiel@nsf.gov*; fax: (703) 292–9154.
Advisory Committee for Computer and Information Science and Engineering, *https://new.nsf.gov/cise/advisory-committee*.	KaJuana Mayberry, Directorate for Computer and Information Science and Engineering; phone: (703) 292–4616; email: *ciseac@nsf.gov*; fax: (703) 292–9454.
Advisory Committee for Cyberinfrastructure, *https://new.nsf.gov/cise/oac/advisory-committee*.	Carl Anderson, Office of Advanced Cyberinfrastructure; phone: (703) 292–4545; email: *cnanders@nsf.gov*; fax: (703) 292–9060.
Advisory Committee for STEM Education, *https://www.nsf.gov/ehr/advisory.jsp*.	Bonnie Green, Directorate for STEM Education; phone: (703) 292–8600; email: *bongreen@nsf.gov*; fax: (703) 292–9179.
Advisory Committee for Engineering, *https://www.nsf.gov/eng/advisory.jsp*.	Cecile Gonzalez, Directorate for Engineering; phone: (703) 292–8300; email: *cjgonzal@nsf.gov*; fax: (703) 292–9467.
Advisory Committee for Geosciences, *https://www.nsf.gov/geo/advisory.jsp*.	Christopher Street, Directorate for Geosciences: phone: (703) 292–8568; email: *cstreet@nsf.gov*; fax: (703) 292–9042.
Advisory Committee for International Science and Engineering, *https://www.nsf.gov/od/oise/advisory.jsp*.	Jessica Libertini, Office of International Science and Engineering, phone: (703) 292–7412; email: *ac-ise@nsf.gov*; fax: (703) 292–9481.

[1] Federally registered lobbyists are not eligible for appointment to these Federal advisory committees.

Advisory committee	Contact person
Advisory Committee for Mathematical and Physical Sciences, *https://www.nsf.gov/mps/advisory.jsp*.	Angela Harris, Directorate for Mathematical and Physical Sciences; phone: (703) 292–8800; email: *amharris@nsf.gov*; fax: (703) 292–9151.
Advisory Committee for Social, Behavioral & Economic Sciences, *https://www.nsf.gov/sbe/advisory.jsp*.	John Garneski, Directorate for Social, Behavioral & Economic Sciences; phone: (703) 292–8700; email: *jgarnesk@nsf.gov*; fax: (703) 292–9083.
Advisory Committee for Technology, Innovation and Partnerships, *https://new.nsf.gov/tip/tip-advisory-commitee*.	Dawn Patterson, Directorate for Technology, Innovation and Partnerships; phone: (703) 292–7009; email: *dpatters@nsf.gov*; fax: (703) 292–9459.
Committee on Equal Opportunities in Science and Engineering, *https://www.nsf.gov/od/oia/activities/ceose/*.	Bernice Anderson, Office of Integrative Activities; phone: (703) 292–8040; email: *banderso@nsf.gov*; fax: (703) 292–9040.
Advisory Committee for Business and Operations, *https://www.nsf.gov/oirm/bocomm/*.	Jeffrey Rich, Office of Information and Resource Management; phone: (703) 292–8100; email: *jrich@nsf.gov*; fax: (703) 292–9369.
Advisory Committee for Environmental Research and Education, *https://www.nsf.gov/ere/ereweb/advisory.jsp*.	Ashley Pierce, Office of Integrative Activities; phone: (703) 292–8040; email: *acere-poc@nsf.gov*; fax: (703) 292–9040.
Astronomy and Astrophysics Advisory Committee, *https://www.nsf.gov/mps/ast/aaac.jsp*.	Carrie Black, Division of Astronomical Sciences; phone: (703) 292–2426; email: *cblack@nsf.gov*; fax: (703) 292–9452.

Dated: April 2, 2024.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2024–07258 Filed 4–4–24; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 52–048; NRC–2024–0065]

NuScale Power, LLC; US600 Standard Design Certification and Standard Design Approval

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) received a June 29, 2023, letter from NuScale Power, LLC (NuScale), which requested an exemption from the annual and 30-day reporting requirements described in NRC regulations for the US600 Standard Design Certification (DC) and Standard Design Approval (SDA), and the Emergency Core Cooling System (ECCS) Evaluation Model (EM) referenced within the request, unless and until that EM is incorporated in a facility license application. The NRC reviewed NuScale's request and determined to grant the exemption.

DATES: The exemption was issued on March 28, 2024.

ADDRESSES: Please refer to Docket ID NRC–2024–0065 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2024–0065. Address questions about Docket IDs to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *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.

FOR FURTHER INFORMATION CONTACT: Stacy Joseph, Senior Project Manager, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3256; email: *Stacy.Joseph@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the exemption is attached.

Dated: April 1, 2024.

For the Nuclear Regulatory Commission.

Brian W. Smith,

Director, Division of New and Renewed Licenses, Office of Nuclear Reactor Regulation.

Attachment—Exemption

Nuclear Regulatory Commission

Docket No. 52–048

NuScale Power, LLC

US600 Standard Design Certification and Standard Design Approval

I. Background

The NuScale Standard Plant Design Certification Application (DCA) was submitted to the NRC on January 6, 2017, pursuant to the requirements of title 10 of the *Code of Federal Regulations* (10 CFR), part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants'' (ML17013A229). NuScale submitted the final version of its Standard Plant DCA, Revision 5, by letter dated July 29, 2020 (ML20225A044), and requested approval of the NuScale design as described in the NuScale DCA, under subpart E, ''Standard Design Approvals,'' of 10 CFR part 52. By letter dated August 28, 2020 (ML20231A804), the NRC informed NuScale that the plant design meets the applicable requirements for the DC stage of licensing, and, on September 11, 2020, the SDA request was granted (ML20247J564). On January 19, 2023, the NRC amended its regulations to certify the NuScale standard design (88 FR 3287).

By letter dated June 29, 2023 (ML23180A151), NuScale requested an exemption from the reporting requirements of 10 CFR 50.46(a)(3)(iii) as applicable to Topical Report ''Loss-of-Coolant Accident Analysis Methodology,'' TR–0516–49422–P–A,

Revision 2 (Non-proprietary version: ML20189A644).

Section 50.46(a)(1)(i) in part provides requirements for models used in calculations regarding Emergency Core Cooling System (ECCS) performance following postulated loss of coolant accidents. Section 50.46(a)(3)(iii) requires that a holder of a standard DC or a holder of a SDA report any change or error found in such ECCS performance models, including the nature of the change or error and its estimated effect on the limiting ECCS analysis, at least annually. The regulation further requires that if the change or error is significant, a report is to be provided within 30 days and include a proposed schedule for reanalysis or other action needed to show compliance with § 50.46 requirements, and requires that the DC or SDA holder propose immediate steps to demonstrate compliance or bring plant design into compliance. A significant change or error is described in section 50.46(a)(3)(i) as one which results in a calculated peak fuel cladding temperature difference by more than 50 °F from the temperature calculated for the limiting transient using the last acceptable model, either alone or in combination with other changes and errors, such that the sum of the absolute magnitudes of the respective temperature changes is greater than 50 °F.

II. Request/Action

In a letter dated June 29, 2023 (ML23180A151), NuScale requested an exemption from both the annual and 30-day reporting requirements of 10 CFR 50.46(a)(3)(iii) as applicable to Topical Report ''Loss-of-Coolant Accident Analysis Methodology,'' TR–0516–49422–P–A, Revision 2 (ML20189A644). Revision 2 of that topical report documents an acceptable ECCS Evaluation Model (EM) and is incorporated by reference in the final safety analysis report supporting NuScale's US600 SDA and DC. NuScale stated that neither the US600 SDA, DC, nor the associated ECCS EM is currently referenced or anticipated to be referenced by an application for constructing or operating a nuclear facility. NuScale stated its intent to resume reporting changes and errors in the event that a future license application references the US600 SDA, DC, or TR–0516–49422–P–A, Revision 2.

III. Discussion

The regulation for which the exemption is sought has two reporting requirements. The first requirement is that changes or errors discovered in an acceptable EM and their effect on the limiting ECCS analysis shall be reported at least annually. The second requirement is that, if those changes or errors are significant, a report shall be provided within 30 days and include a schedule for providing reanalysis or other action needed to show compliance, and a proposal of immediate steps to bring the plant design into compliance. A significant change or error, as it relates to this regulation, is defined as one which results in a calculated peak fuel cladding temperature difference by more than 50 °F from the last acceptable model.

As discussed below, the NRC staff reviewed this request and determined that it is appropriate to grant the exemption, in accordance with the regulations as the exemption does not present an undue risk to public health or safety, is consistent with the common defense and security, and special circumstances exist.

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50, including 10 CFR 50.46(a)(3)(iii), when: (1) the exemptions are authorized by law, will not present an undue risk to public health or safety, and are consistent with the common defense and security; and (2) special circumstances are present. As stated in the regulation, and as relevant to the requested exemption, special circumstances may exist if application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule (10 CFR 50.12(a)(2)(ii)).

The purpose of 10 CFR 50.46(a)(3)(iii) is to provide timely reporting to the NRC regarding the nature and estimated effect of any change or error in the limiting ECCS analysis. In its request, NuScale committed to perform necessary reporting to a reactor license applicant and the NRC if the US600 SDA, DC, or TR–0516–49422–P–A, Revision 2, is referenced by a future applicant. The staff notes that 10 CFR 50.46(a)(3)(ii) requires an applicant that seeks to construct or operate a facility using the design to make similar reports. Further, 10 CFR 50.46(a)(3)(i) requires a DC or SDA holder to estimate the effect of any change to or error in an acceptable EM or in the application of such a model to determine if the change or error is significant, ensuring that changes and errors would continue to be documented internally by the DC or SDA holders, and be available for NRC inspection. The staff also notes that 10 CFR 50.46(a)(3)(iii) requires not only that changes or errors in the ECCS EM be reported, but also that changes or errors in the application of the EM be reported. Since TR–0516–49422–P–A, Revision 2, was incorporated by reference into the approved SDA and DC for the design, in the event that the SDA or DC is referenced by a future applicant, compliance with 10 CFR 50.46(a)(3)(iii) would need to include both changes or errors in the ECCS EM, as well as changes or errors in the application of the EM.

No Undue Risk to Public Health and Safety

The purpose of 10 CFR 50.46(a)(3)(iii) is to provide for timely notification of the nature and estimated effect of any errors or changes in the limiting ECCS analysis. In the absence of any application to utilize the referenced design for constructing or operating a nuclear facility, there is no undue risk to public health and safety. The requested exemption is administrative in nature and pertains only to the requirements for reporting in 10 CFR 50.46(a)(3)(iii). No new accident precursors would be created as a result of the requested exemption; therefore, neither the probability nor the consequences of postulated accidents would be increased. The reporting of any changes or errors in the limiting ECCS analysis would resume when an application for a license that references the US600 SDA, DCA or the associated ECCS EM is submitted to the NRC. The request for an exemption from the annual and 30-day reporting requirements therefore have no bearing on public health and safety and poses no undue risk to public health and safety.

Consistent With Common Defense and Security

The requested exemption is administrative in nature and pertains only to the requirements for reporting in 10 CFR 50.46(a)(3)(iii). In the absence of any application to utilize the referenced design, this exemption has no relation to security issues; therefore, the common defense and security is not impacted.

Special Circumstances

Special circumstances, in accordance with 10 CFR 50.12(a)(2), may be present relevant to the requested exemption. Specifically, 10 CFR 50.12(a)(2)(ii) states, in part, that special circumstances may exist if application

of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule.

The underlying purpose of 10 CFR 50.46(a)(3)(iii) is to ensure that the NRC receives timely notification of the nature and estimated effect of errors or changes in the limiting ECCS analysis for a design or facility. These requirements for holders of SDAs and DCs were added to 10 CFR 50.46 in 2007 (72 FR 49352), with the Statements of Consideration noting that, ''[c]onforming references to design approvals, design certifications, and licenses issued under part 52 were made to § 50.46, so that the NRC will be notified of changes to or errors in acceptable EMs, or the application of such models, that were used in licenses, certifications, and approvals issued under part 52.'' For designs that are not yet referenced in an application for constructing or operating a nuclear facility, the NRC staff's review of any changes or errors noted in the annual report is generally performed to confirm that the design continues to comply with the acceptance criteria in 10 CFR 50.46(b). Considering the ample margin in the US600 design relative to the ECCS acceptance criteria in 10 CFR 50.46(b), the NRC staff has reasonable assurance that reporting of changes or errors as part of the annual reporting requirement is not necessary to assure continued compliance with the applicable acceptance criteria.

NuScale's exemption request also includes a request for exemption from the 30-day reporting requirement pertaining to significant changes or errors and associated corrective actions. Timely notice to the NRC of significant underlying changes or errors and associated corrective actions is valuable because it enables the NRC staff to evaluate the continued ability of the SDA or DC to comply with the acceptance criteria in 10 CFR 50.46(b) in a timely manner. As discussed in the Statements of Consideration accompanying the 10 CFR part 52 final rule (54 FR 15372), that rule was intended to achieve the early resolution of licensing issues, thereby enhancing the safety and reliability of nuclear power plants and reducing the complexity and uncertainty of the licensing process. As described previously, 10 CFR 50.46(a)(3)(i) requires a DC or SDA holder to estimate the effect of any change to or error in an acceptable EM or in the application of such a model to determine if the change or error is significant, ensuring that changes and errors would continue to be documented internally by the DC or SDA holders, and be available for NRC inspection. If the NRC receives an application that references the NuScale DC, SDA, or TR–0516–49422–P–A, Rev. 2, NuScale, as the DC and SDA holder, will be required to resume the reporting requirements of 10 CFR 50.46(a)(iii). By complying with the 10 CFR 50.46(a)(i) requirement to internally document any changes or errors in the accepted EM or application of the model, the applicant and the NRC would still be able to achieve resolution of such issues early in the licensing process and continue to reduce uncertainty in the licensing process, thereby achieving the underlying purpose of the rule. The staff also notes that an applicant to construct or operate a plant utilizing the DC or SDA design would be responsible for providing an acceptable analysis of the ECCS in its application to the NRC.

Therefore, for the above stated reasons, the NRC staff finds that NuScale's compliance with the reporting requirements, prior to the submittal of any application to utilize the referenced design, is not necessary to achieve the underlying purpose of the rule, and that special circumstances for the requested exemption from the annual and 30-day reporting requirements in 50.46(a)(3)(iii) are present under 10 CFR 50.12(a)(2)(ii).

Eligibility for Categorical Exclusion From Environmental Review

With respect to the exemption's impact on the quality of the human environment, the NRC staff has determined that the exemption from reporting that was requested by NuScale is eligible for categorical exclusion as identified in 10 CFR 51.22(c)(25), in that:

(i) There is no significant hazards consideration;

The criteria for determining whether there is no significant hazards consideration are found in 10 CFR 50.92. The proposed action involves only a change regarding the requirements for the submission of reports on errors or changes in the ECCS analysis and EM for the US600 DC and SDA, neither of which has yet been referenced by an applicant or licensee seeking to utilize either design or to utilize the referenced EM. The reporting of changes or errors would have no bearing on the operation of any operating reactor, or any existing application to construct or operate a reactor, prior to the submittal of an application to utilize either design. Therefore, there is no significant hazards consideration because granting the proposed exemption would not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or

(3) Involve a significant reduction in a margin of safety.

(ii) There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite;

The proposed action involves only a change to reporting requirements and does not have any bearing on the operation of any operating reactor, or any application to construct or operate a reactor, and does not involve any changes in the types or any significant increase in the amounts of effluents that may be released offsite.

(iii) There is no significant increase in individual or cumulative public or occupational radiation exposure;

Since the proposed action involves only a change to reporting requirements and does not have any bearing on the operation of any operating reactor, or any application to construct or operate a reactor, the exemption does not contribute to any significant increase in occupational or public radiation exposure.

(iv) There is no significant construction impact;

The proposed action involves only a change to reporting requirements, which is administrative in nature. This DC and SDA have not yet been referenced by any applicant to construct or operate a reactor. Accordingly, the proposed action does not involve any construction impact.

(v) There is no significant increase in the potential for or consequences from radiological accidents;

The proposed action involves only a change to reporting requirements and does not have any bearing on the operation of an operating reactor, or any application to construct or operate a reactor, and it therefore does not impact the probability or consequences of radiological accidents. In the future, if an application to construct or operate a reactor utilizing the SDA or DC design, or referencing the applicable EM, is submitted, the reporting requirements would be triggered, and the NRC's consideration of the requested licensing action would necessarily include consideration of those reports in evaluating the potential for or consequences of radiological accidents.

(vi) The requirements from which an exemption is sought involve:

(1) Reporting requirements;

The exemption request involves submitting the annual and 30-day

reports required by 10 CFR 50.46(a)(3)(iii); and

(2) Scheduling requirements;

The proposed exemption relieves that applicant from submitting the required reports until NRC receives a request to reference the NuScale US600 DC, SDA or Topical Report TR–0516–49422–P–A, Revision 2 (ML20189A644). If an application to use the US600 SDA, DC, or TR–0516–49422–P–A, Revision 2, is referenced in a license application, NuScale will then be required to submit the reports required by regulation to the NRC.

Based on the discussion above, the NRC staff concludes that the exemption request meets the requirements in 10 CFR 51.22(c)(25) and is eligible for categorical exclusion from environmental review.

IV. Conclusion

For the reasons discussed in Section III.B above, the NRC concludes that NuScale's requested exemption from the annual and 30-day reporting requirements in 10 CFR 50.46(a)(3)(iii) satisfies the applicable requirements in 10 CFR 50.12 and should be granted. The exemption from the annual and 30-day reporting requirements is effective upon issuance.

Dated March 28, 2024.

For The Nuclear Regulatory Commission.

/RA/

Brian Smith, Director,

Division of New and Renewed Licenses, Office of Nuclear Reactor Regulation.

[FR Doc. 2024–07210 Filed 4–4–24; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2023–0150]

Information Collection: Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste

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, ''Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste.''

DATES: Submit comments by June 4, 2024. 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; 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–2023–0150. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* David Cullison, 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: David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2023–0150 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–2023–0150.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The supporting statement and burden spreadsheet are available in ADAMS under Accession Nos. ML23317A189 and ML23317A192, 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 Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2023–0150, 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 below.

1. *The title of the information collection:* 10 CFR part 72, Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste.

2. *OMB approval number:* 3150–0132.

3. *Type of submission:* Extension.

4. *The form number, if applicable:* Not applicable.

5. *How often the collection is required or requested:* Required reports are collected and evaluated on a continuing basis as events occur; submittal of reports varies from less than one per year under some rule sections to up to an average of about 80 per year under other rule sections. Applications for new licenses, certificates of compliance (CoCs), and amendments may be submitted at any time; applications for renewal of licenses are required every 40 years for an independent spent fuel storage installation (ISFSI) or CoC effective May 21, 2011, and every 40 years for a monitored retrievable storage (MRS) facility.

6. *Who will be required or asked to respond:* Certificate holders and applicants for a CoC for spent fuel storage casks; licensees and applicants for a license to possess power reactor spent fuel and other radioactive materials associated with spent fuel storage in an ISFSI; and the Department of Energy for licenses to receive, transfer, package and possess power reactor spent fuel, high-level waste, and other radioactive materials associated with spent fuel and high-level waste storage in an MRS.

7. *The estimated number of annual responses:* 858.

8. *The estimated number of annual respondents:* 89.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 78,466.

10. *Abstract:* 10 CFR part 72, establishes mandatory requirements, procedures, and criteria for the issuance of licenses to receive, transfer, and possess power reactor spent fuel and other radioactive materials associated with spent fuel storage in an ISFSI, as well as requirements for the issuance of licenses to the Department of Energy to receive, transfer, package, and possess power reactor spent fuel and high-level radioactive waste, and other associated radioactive materials in an MRS. The information in the applications, reports, and records is used by NRC to make licensing and other regulatory determinations.

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: April 2, 2024.

For the Nuclear Regulatory Commission.

David Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2024–07286 Filed 4–4–24; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2023–0154]

Information Collection: Reactor Site Criteria

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, ''Reactor Site Criteria.''

DATES: Submit comments by June 4, 2024. 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–2023–0154. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* David Cullison, 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: David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2023–0154 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–2023–0154. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2023–0154 on this website.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The supporting statement is available in ADAMS under Accession No. ML23242A273.
- *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 Clearance Officer, David C. Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2023–0154, 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 below.

1. *The title of the information collection:* Reactor Site Criteria.

2. *OMB approval number:* 3150–0093.

3. *Type of submission:* Extension.

4. *The form number, if applicable:* Not applicable.

5. *How often the collection is required or requested:* As necessary in order for the NRC to assess the adequacy of proposed seismic design bases and the design bases for other site hazards for small modular reactors (SMRs) and/or non-light water reactors (LWRs) constructed and licensed in accordance with parts 50 and 52 of title 10 of the *Code of Federal Regulations* (10 CFR) and the Atomic Energy Act of 1954, as amended.

6. *Who will be required or asked to respond:* Applicants who apply for an early site permit (ESP), combined license (COL) or a construction permit (CP) or operating license (OL) on or after January 10, 1997.

7. *The estimated number of annual responses:* 13.

8. *The estimated number of annual respondents:* 13.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 482,412 hours.

10. *Abstract:* 10 CFR part 100, ''Reactor Site Criteria,'' establishes approval requirements for proposed sites for the purpose of constructing and operating stationary SMRs and/or non-LWRs. Subpart B, ''Evaluation Factors for Stationary Power Reactor Site Applications on or After January 10, 1997,'' requirements apply to applicants who apply for an ESP, COL or a CP or OL on or after January 10, 1997. This clearance is necessary since the NRC is expecting approximately 8 SMR and/or non-LWR siting applications over the next 3 years. The applicants must provide information regarding the physical characteristics of the site in addition to the potential for natural phenomena and man-made hazards. This includes information on meteorological hazards (such as hurricanes, tornadoes, snowfall, and extreme temperatures), hydrologic hazards (such as floods, tsunami, and seiches) geologic hazards (such as faulting, seismic hazards, and the maximum credible earthquake) and factors such as population density, the proximity of man-related hazards (*e.g.,* airports, dams, transportation routes, military and chemical facilities), and site hydrological and atmospheric dispersion characteristics. The NRC staff reviews the submitted information and, if necessary, may generate a request for additional information. The staff meets with the applicant and conducts a site visit to resolve any open issues. When the open issues have been resolved, the staff writes the final safety evaluation report, which is published and used as a basis for the remainder of the NRC licensing process.

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: April 1, 2024.

For the Nuclear Regulatory Commission.

David Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2024–07207 Filed 4–4–24; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–250 and 50–251; NRC–2022–0172]

Florida Power & Light Company; Turkey Point Nuclear Generating Unit Nos. 3 and 4; Final Site-Specific Environmental Impact Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing final site-specific environmental impact statement (EIS) NUREG–1437, Supplement 5a, Second Renewal, ''Site-Specific Environmental Impact Statement for License Renewal of Nuclear Plants Regarding Subsequent License Renewal for Turkey Point Nuclear Generating Unit Nos. 3 and 4, Final Report.'' This EIS is related to the subsequent renewal of Renewed Facility Operating License Nos. DPR–31 and DPR–41 for an additional 20 years of operation for Turkey Point Nuclear Generating Unit Nos. 3 and 4 (Turkey Point). Turkey Point is located in Homestead, Florida, approximately 25 miles south-southwest of Miami. Possible alternatives to the proposed action of subsequent license renewal for Turkey Point include the no-action alternative and reasonable replacement power and alternative cooling water system alternatives.

DATES: NUREG–1437, Supplement 5a, Second Renewal, is available as of March 29, 2024.

ADDRESSES: Please refer to Docket ID NRC–2022–0172 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0172. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System*

(ADAMS): You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* NUREG–1437, Supplement 5a, Second Renewal, is available in ADAMS under Accession No. ML24087A061.

- *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.
- *Public Library:* NUREG–1437, Supplement 5a, Second Renewal, will be available for public inspection at the Naranja Branch Library, 14850 SW 280th Street, Homestead, Florida 33032.

FOR FURTHER INFORMATION CONTACT: Lance J. Rakovan, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2589; email: *Lance.Rakovan@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 51.118 of title 10 of the *Code of Federal Regulations* (10 CFR), the NRC is making available for public inspection NUREG–1437, Supplement 5a, Second Renewal, regarding the subsequent renewal of Florida Power & Light Company's (FPL) Renewed Facility Operating License Nos. DPR–31 and DPR–41 for an additional 20 years of operation for Turkey Point. A notice of availability of the draft of NUREG–1437, Supplement 5a, Second Renewal, was published in the **Federal Register** on September 8, 2023, by the NRC (88 FR 62110) and by the Environmental Protection Agency (88 FR 62078). The public comment period on the draft EIS ended on November 7, 2023, and the comments received are addressed in the final EIS.

II. Discussion

As discussed in Chapter 3 of NUREG–1437, Supplement 5a, Second Renewal, the NRC staff's recommendation is that the adverse environmental impacts of subsequent license renewal for Turkey Point for an additional 20 years beyond the expiration dates of the initial renewed licenses are not so great that preserving the option of subsequent license renewal for energy-planning decisionmakers would be unreasonable. This recommendation is based on: (1) FPL's environmental report, as supplemented; (2) the NRC staff's consultations with Federal, State, Tribal, and local government agencies; (3) the NRC staff's independent environmental review, which is documented in NUREG–1437, Supplement 5a, Second Renewal; and (4) the NRC staff's consideration of public comments.

Dated: April 1, 2024.

For the Nuclear Regulatory Commission.

John M. Moses,

Deputy Director, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2024–07152 Filed 4–4–24; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99875; File No. SR–CboeEDGA–2024–009]

Self-Regulatory Organizations; Cboe EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fees Schedule To Adopt Fees for Dedicated Cores

April 1, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 20, 2024, Cboe EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA Equities'') proposes to amend its Fees Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/edga/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its fee schedule to adopt fees relating to the use of Dedicated Cores.[3]

The Exchange proposes to introduce a new connectivity offering relating to the use of Dedicated Cores. By way of background, all Central Processing Units (''CPU Cores'') have historically been shared by logical order entry ports (*i.e.,* multiple logical ports from multiple firms may connect to a single CPU Core). Starting February 26, 2024, the Exchange began to allow Users[4] to assign a single BOE logical entry port to a single dedicated CPU Core (''Dedicated Core'').[5] Use of Dedicated Cores can provide reduced latency, enhanced throughput, and improved performance since a firm using a Dedicated Core is utilizing the full processing power of a CPU Core instead of sharing that power with other firms. This offering is completely voluntary

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] On March 19, 2024, the Exchange filed a proposal to introduce Dedicated Cores (SR–CboeEDGA–2024–008).

[4] A User may be either a Member or Sponsored Participant. The term ''Member'' shall mean any registered broker or dealer that has been admitted to membership in the Exchange. limited liability company or other organization which is a registered broker or dealer pursuant to Section 15 of the Act, and which has been approved by the Exchange. A Sponsored Participant may be a Member or non-Member of the Exchange whose direct electronic access to the Exchange is authorized by a Sponsoring Member subject to certain conditions. See Exchange Rule 11.3.

[5] The Exchange notes that firms will not have physical access to their Dedicated Core and thus cannot make any modifications to the Dedicated Core or server. All Dedicated Cores (including servers used for this service) are owned and operated by the Exchange.

and is available to all Users that wish to purchase Dedicated Cores. Users will also continue to have the option to utilize BOE logical order entry ports on shared CPU Cores as they do today, either in lieu of, or in addition to, their use of Dedicated Core(s). As such, Users will be able to operate across a mix of shared and dedicated CPU Cores which the Exchange believes provides additional risk and capacity management. Further, Dedicated Cores are not required nor necessary to participate on the Exchange and as such Users may opt not to use Dedicated Cores at all.

The Exchange is proposing to assess the following monthly fees for those Users that wish to use Dedicated Cores: $650 per Dedicated Core for the first 3 Dedicated Cores; $1,050 per Dedicated Core for the 4th–6th Dedicated Cores; and $1,450 per Dedicated Core for 7 or more Dedicated Cores. The proposed fees are progressive, and the Exchange proposes to include the following example in the Fees Schedule to provide clarity as to how the fees will be applied. In particular, if a firm chooses to purchase 5 Dedicated Cores, that firm will be assessed a total monthly fee of $4,050 for use of those Dedicated Cores (*i.e.,* $650 × 3 Dedicated Cores and $1,050 × 2 Dedicated Cores). The Exchange also proposes to make clear in the Fees Schedule that the monthly fees are assessed and applied in their entirety and are not prorated. The monthly Dedicated Core fees are in addition to the standard per port fee assessed to Users for the BOE Logical Port(s) ports assigned to the Dedicated Core(s). The Exchange notes the current standard fees assessed for BOE Logical Ports, whether used with Dedicated or shared CPU cores, will remain applicable and unchanged.[6]

Since the Exchange currently has finite amount of space in its data centers in which its servers (and therefore corresponding CPU Cores) are located, the Exchange also proposes to prescribe a maximum limit on the number of Dedicated Cores that Users may purchase each month. Particularly, the Exchange proposes to provide that Members will be limited to a maximum number of 10 Dedicated Cores[7] and Sponsoring Members will be limited to a maximum number of 4 Dedicated Cores for each of their Sponsored Access relationships.[8] The purpose of establishing these limits is to manage the allotment of Dedicated Cores in a fair manner and to prevent the Exchange from being required to expend large amounts of resources in order to provide an unlimited number of Dedicated Cores.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[9] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[10] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[11] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(4)[12] of the Act, which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Members and other persons using its facilities.

The Exchange believes the proposed fees are reasonable because Dedicated Cores provide a valuable service in that it may provide reduced latency, enhanced throughput, and improved performance compared to use of a shared CPU Core since a firm using a Dedicated Core is utilizing the full processing power of a CPU Core. The Exchange also emphasizes however, that the use of Dedicated Cores is not necessary for trading and as noted above, is entirely optional. Indeed, Users can continue to access the Exchange through shared CPU Cores at no additional cost. Depending on a firm's specific business needs, the proposal enables Users to choose to use Dedicated Cores in lieu of, or in addition to, shared CPU Cores (or as noted, not use Dedicated Cores at all). The Exchange believes the proposal to operate across a mix of shared and dedicated CPU Cores may further provide additional risk and capacity management. If a User finds little benefit in having Dedicated Cores, or determines Dedicated Cores are not cost-efficient for its needs or does not provide sufficient value to the firm, such User may continue its use of the shared CPU Cores, unchanged. Indeed, the Exchange has no plans to eliminate shared CPU Cores nor to require Users to purchase Dedicated Cores.

The Exchange also believes that the proposed Dedicated Core fees are equitable and not unfairly discriminatory because they would be assessed uniformly to similarly situated users in that all Users who choose to purchase Dedicated Cores will be subject to the same proposed tiered fee schedule. The Exchange believes the proposed ascending fee structure is also reasonable, equitable and not unfairly discriminatory as it is designed so that firms that use a higher allotment of the Exchange's finite number of Dedicated Cores pay higher rates, rather than placing that burden on market participants that have more modest needs who will have the flexibility of obtaining Dedicated Cores at lower price points in the lower tiers. As such, the proposed fees do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the ascending fee structure reflects the resources consumed by the various needs of market participants—that is, the lowest Dedicated Core consuming Users pay the least, and highest Dedicated Core consuming Users pay the most. Other exchanges similarly assess higher fees to those that consume more Exchange resources.[13] It's also designed to encourage firms to manage their needs in a fair manner and to prevent the Exchange from being required to expend large amounts of resources in order to provide an additional number of Dedicated Cores.

[6] *See* Cboe U.S. Equities Fees Schedules, EDGA Equities, Logical Port Fees.

[7] Members will be limited to 10 Dedicated Cores, regardless of whether they purchase the Dedicated Cores directly and/or through a Service Bureau. In a Service Bureau relationship, a customer allows its MPID to be used on the ports of a technology provider, or Service Bureau. One MPID may be allowed on several different Service Bureaus.

[8] The Exchange announced the initial limit via Exchange Notice which was issued on January 29, 2024. *https://cdn.cboe.com/resources/release_notes/2024/Cboe-Global-Markets-to-Introduce-Cboe-Dedicated-Cores-for-EDGA-Equities.pdf.*

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] *Id.*

[12] 15 U.S.C. 78f(b)(4).

[13] *See e.g.,* MIAX Pearl Equities Exchange Fees Schedule, Section 2(d) Port Fees. *See also* Cboe U.S. Options Fees Schedule, BZX Options, Options Logical Port Fees, Ports with Bulk Quoting Capabilities.

The Exchange believes it is reasonable to limit the number of Dedicated Cores Users can purchase because the Exchange has a finite amount of space in its data centers and availability of cores. The Exchange will continually monitor market participant demand and resource availability and endeavor to adjust the limit if and when the Exchange is able to accommodate additional CPU Cores (including Dedicated Cores). The Exchange monitors its capacity and data center space and thus is in the best place to determine these limits and modify them as appropriate in response to changes to this capacity and space. The proposed limits also apply uniformly to similarly situated market participants (*i.e.* all Members are subject to the same limit and all Sponsored Participants are subject to the same limit, respectively). The Exchange believes it's not unfairly discriminatory to provide for different limits for different types of users. For example, the Exchange believe it's not unfairly discriminatory to provide for an initial lower limit to be allocated for Sponsored Participants because unlike Members, Sponsored Participants are able to access the Exchange without paying a Membership Fee. Members also have more regulatory obligations and risk that Sponsored Participants do not. For example, while Sponsored Participants must agree to comply with the Rules of the Exchange, it is the Sponsoring Member of that Sponsored Participant that remains ultimately responsible for all orders entered on or through the Exchange by that Sponsored Participant. The industry also has a history of applying fees differently to Members as compared to Sponsored Participants.[14]

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 intramarket competition that is not necessary in furtherance of the purposes of the Act because the proposed tiered fee structure will apply equally to all similarly situated Users that choose to use Dedicated Cores. As discussed above, Dedicated Cores are optional and Users may choose to utilize Dedicated Cores, or not, based on their view of the additional benefits and added value provided by utilizing a Dedicated Core. The Exchange believes the proposed fee will be assessed proportionately to the potential value or benefit received by Users with a greater number of Dedicated Cores and notes that Users may determine at any time to cease using Dedicated Cores. As discussed, Users can also continue to access the Exchange through shared CPU Cores at no additional cost.

Next, the Exchange believes the proposed rule change does not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As previously discussed, the Exchange operates in a highly competitive market, including competition for exchange memberships. Market Participants have numerous alternative venues that they may participate on, including 15 other equities exchanges, as well as off-exchange venues, where competitive products are available for trading. Indeed, participants can readily choose to submit their order flow to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current 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.'' [15] The fact that this market is competitive has also long been recognized by the courts. In NetCoalition v. Securities and Exchange Commission, the D.C. Circuit stated as follows: ''[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'. . . .''.[16] Accordingly, the Exchange does not believe its proposed change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [17] and paragraph (f) of Rule 19–b4 [18] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeEDGA–2024–009 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–CboeEDGA–2024–009. 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 submission, all subsequent

[14] *See e.g.,* Securities Exchange Act Release No. 68342 (December 3, 2012) 77 FR 73096 (December 7, 2012) (SR–CBOE–2012–114) and Securities Exchange Act Release No. 66082 (January 3, 2012) 77 FR 1101 (January 9, 2012) (SR–C2–2011–041).

[15] See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[16] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4(f).

amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also 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–CboeEDGA–2024–009 and should be submitted on or before April 26, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–07223 Filed 4–4–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99872; File No. SR–NYSEAMER–2024–23]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Change To Amend Rules 7.4E, 64, 236, and 257, as Well as Sections 510, 512, and 521 of the NYSE American LLC Company Guide

April 1, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 25, 2024, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rules 7.4E, 64, 236, and 257, as well as Sections 510, 512, and 521 of the NYSE American LLC Company Guide, to conform to amendments to Rule 15c6–1(a) of the Act to shorten the standard settlement cycle for most broker-dealer transactions from two business days after the trade date (''T+2'') to one business day after the trade date (''T+1''). The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

On March 6, 2023, the Commission adopted amendments to Rule 15c6–1(a) of the Act to shorten the standard settlement cycle for most broker-dealer transactions from T+2 to T+1.[3] Accordingly, the Exchange proposes to amend the rules identified below to conform with the amendments to Rule 15c6–1(a) and reflect a standard settlement cycle of T+1:

- Rule 7.4E (Ex-Dividend or Ex-Rights Dates)
- Rule 64 (Equities. Bonds, Rights and 100-Share-Unit Stocks)
- Rule 236 (Equities.Ex-Warrants)
- Rule 257 (Equities. Deliveries After 'Ex' Date)
- Section 510 of the NYSE American LLC Company Guide (Two Day Delivery Plan)
- Section 512 of the NYSE American LLC Company Guide (Ex-Dividend Procedure)

Proposed Rule Change

The Exchange proposes the following changes to reflect a T+1 settlement cycle.

- Rule 7.4E currently provides that transactions in stocks traded regular way are generally ''ex-dividend'' or ''ex-rights'' on the business day preceding the record date or the date of the closing of transfer books, or else on the second preceding business day when the record date or closing of transfer books occurs on a non-business day. To reflect settlement on T+1 rather than T+2, the Exchange proposes to amend this rule to provide that transactions would be ex-dividend or ex-rights on the record date or date of the closing of transfer books, or on the preceding business day when the record date or closing of transfer books occurs on a non-business day.
- Current Rule 64(a)(i) defines regular way delivery as occurring on the second business day following the day of the contract. To conform with the transition to a T+1 settlement cycle, the Exchange proposes to amend Rule 64(a)(i) to delete the word ''second,'' such that the rule would provide that regular way delivery occurs on the business day following the day of the contract.[4]
- Current Rule 236[5] provides that ex-warrant trading will begin on the business day preceding the date of expiration of the warrants, except that when expiration occurs on a non-business day, it will begin on the second business day preceding expiration. To conform with a T+1 settlement cycle, the Exchange proposes to delete the phrase ''the business day preceding,'' such that the rule would provide that these transactions would be ex-warrants on the date of expiration, and the word ''second,'' such that the rule would provide for expiration on the business day preceding expiration when

[19] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 96930, 88 FR 13872 (March 6, 2023) (''T+1 Adopting Release'').

[4] The Exchange also proposes to delete the obsolete parenthetical reference to Rule 14 in current Rule 64(a)(i), as Rule 14 is not applicable to trading on the Pillar platform. *See* Securities Exchange Act Release No. 82212 (December 4, 2017), 82 FR 58036 (December 8, 2017) (SR–NYSEAMER–2017–34) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Exchange Rules To Delete Obsolete Cash Equities Rules That Are Not Applicable to Trading on the Pillar Trading Platform and To Delete Other Obsolete Rules). The Exchange further proposes to delete Rules 64(a)(ii), 64(b), and 64(c), as the non-regular way settlement options described in such rules are no longer available on the Exchange. *See id.* The Exchange also proposes non-substantive conforming changes in Rule 64(a) to reflect the deletion of Rules 64(a)(ii), 64(b), and 64(c).

[5] The Exchange also proposes to amend the section header above Rule 236 to conform it with the current title and substance of Rule 236.

expiration occurs on a non-business day.[6]

• Current Rule 257 provides that when a security is sold before it is ex-dividend or ex-rights and delivery is made too late to enable the buyer to obtain transfer in time to become a holder of record to receive the distribution to be made with respect to such security, the seller shall pay or deliver the distribution to the buyer as set forth in this rule. In the case of stock dividends or rights to subscribe, the seller must deliver to the buyer within two days after the record date either the dividend or rights (or due-bill for the same). In the case of cash dividends, the seller must deliver to the buyer within two days after the record date a due-bill-check for the amount of the dividend. The Exchange proposes to amend Rule 257 to replace the references to ''two days after the record date'' with references to ''one day after the record date,'' to conform with the transition to a T+1 settlement cycle.[7]

• Section 510 of the NYSE American LLC Company Guide provides that transactions effected regular way on the Exchange are due for settlement in two business days. To conform with the transition from T+2 to T+1 settlement, the Exchange proposes to amend Section 510 to provide that transactions on the Exchange will be settled in one business day and are due for settlement on the business day after the transaction date. The Exchange further proposes to amend the days of the week in the example provided in Section 510 from Tuesday to Monday and from Wednesday to Tuesday, to reflect the shortened settlement cycle.

• Section 512 of the NYSE American LLC Company Guide currently provides that transactions are ex-dividend on the business day preceding the record date, except that if the record date is not a business day, the transaction would be ex-dividend on the second preceding business day. To conform with T+1 settlement, the Exchange proposes to amend Section 512 to provide that transactions would be ex-dividend on the record date or, if the record date is a non-business day, on the preceding business day.[8]

Implementation

The Exchange proposes that the operative date of this proposed rule change will be Tuesday, May 28, 2024, which is the compliance date specified in the T+1 Adopting Release, or such later date as may be announced by the Commission for compliance with the amendments to Rule 15c6–1(a) set forth in the T+1 Adopting Release.[9] With the implementation of the T+1 settlement cycle and as described in the proposed changes outlined above, the ex-dividend date for ''normal'' distributions will be the same business day as the record date. Accordingly, the Exchange proposes that Wednesday, May 29, 2024 would be the first date to which the proposed rules described herein would apply (*i.e.,* the first record date to which the new ex-dividend date rationale will be applied). During the implementation of the T+1 settlement cycle, the Exchange proposes that the ex-dividend dates will be as follows:

Record date	Ex-dividend date
May 24, 2024	May 23, 2024.
May 28, 2024	May 24, 2024.
May 29, 2024	May 29, 2024.

A record date of Friday, May 24, 2024 would be a date prior to the effective date of the amendments to Rule 15c6–1(a) of the Act to shorten the standard settlement cycle for most broker-dealer transactions from T+2 to T+1.[10] The rules described above would apply to this record date in their current form and, thus, the ''ex-dividend date'' would be the first business day preceding the record date or Thursday, May 23, 2024. Monday, May 27, 2024 is Memorial Day, which is an Exchange holiday; accordingly, there would be no record date on a holiday. A record date of Tuesday, May 28, 2024 would also fall under the Exchange's current rules, and the first business day preceding such record date would be Friday, May 24, 2024. On Wednesday, May 29, 2024, the proposed rules described above would apply, such that, for the record date of May 29, 2024, the ''ex-dividend date'' would be the same business day.

The Exchange will issue a Trader Notice regarding the implementation of the proposed rule change and T+1 settlement cycle, which date would correspond with the industry-led transition to a T+1 standard settlement, and the compliance date of the Commission's amendment of Rule 15c6–1(a) of the Act to require standard settlement no later than T+1.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Section 6(b)(5) of the Act,[12] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, 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 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.

In particular, the proposed rule change would amend the Exchange's rules to reflect a standard settlement cycle of T+1, in support of the industry-led initiative to shorten the settlement cycle to one business day. Moreover, the proposed rule change is consistent with the Commission's amendments to Rule 15c6–1(a) of the Act to require standard settlement no later than T+1. The Exchange believes that the proposed rule change would provide regulatory certainty to facilitate the industry-led move to a T+1 settlement cycle. The Exchange further believes that, by shortening the time period for settlement of most securities transactions, the proposed rule change would protect investors and the public interest by reducing the number of unsettled trades in the clearance and settlement system at any given time, thereby reducing the risk inherent in settling securities transactions to clearing corporations, their members, and public investors.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue, but rather to support the industry's transition to a T+1 regular-way settlement cycle in conformity with the Commission's amendment of Rule 15c6–1(a). The proposed change amends the Exchange's rules pertaining to securities settlement, which rules would apply uniformly to all contracts for the purchase or sale of a security (other than exempted securities) that provide for payment of funds and delivery of securities that occur on the Exchange or

[6] The Exchange also proposes to delete the parenthetical reference to Rule 14 because, as noted above, Rule 14 is no longer applicable to trading on the Exchange. *See* note 4, *supra.*

[7] The Exchange further proposes to delete the reference to Rule 14 because, as noted above, Rule 14 is no longer applicable to trading on the Exchange. *See* note 4, *supra.*

[8] The Exchange also proposes to delete references to cash transactions in Section 521 as obsolete. *See* note 4, *supra.*

[9] *See* note 3, *supra.*

[10] *See* note 3, *supra.*

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

other self-regulatory organizations and is intended to facilitate the industry-wide transition to a T+1 settlement cycle. The Exchange also believes that the proposed rule change will serve to promote clarity and consistency in its rules, thereby reducing burdens on the marketplace and facilitating investor protection. Accordingly, the Exchange believes that the proposed changes do not impose any burden on competition other than that necessary to implement the amendments to Rule 15c6–1(a) of the Act as set forth in the T+1 Adopting Release.[13]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) significantly affect the protection of investors or the public interest;

(ii) impose any significant burden on competition; and

(iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSEAMER–2024–23 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–NYSEAMER–2024–23. 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 submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also 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–NYSEAMER–2024–23 and should be submitted on or before April 26, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–07220 Filed 4–4–24; 8:45 am]

BILLING CODE 8011–01–P

[13] *See* note 3, *supra.*

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99877; File No. SR–CboeEDGX–2024–018]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 2.8 Regarding Voluntary Termination of Rights as an Exchange Member

April 1, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 19, 2024, Cboe EDGX Exchange, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') proposes to amend Rule 2.8, related to the voluntary termination of rights as an Exchange Member (''Member'').[5] The text of the proposed rule change is provided below.

(Additions are *italicized;* deletions are [bracketed])

* * * * *

Rules of Cboe EDGX Exchange, Inc.

* * * * *

Rule 2.8. Voluntary Termination of Rights as a Member

A Member may voluntarily terminate its rights as a Member only by a written resignation addressed to the Exchange's Secretary or another officer designated by the Exchange. [Such resignation shall not take effect until 30 days after all of the following conditions have been satisfied: (i) receipt of such written resignation; (ii) all indebtedness due the Exchange shall have been paid in full; (iii) any Exchange investigation or

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* Exchange Rule 1.5(n). The term ''Member'' is defined as ''any registered broker or dealer that has been admitted to membership in the Exchange.''

disciplinary action brought against the Member has reached a final disposition; and (iv) any examination of such Member in process is completed and all exceptions noted have been reasonably resolved; provided, however, that the Board may declare a resignation effective at any time] *Each terminating Member must promptly (a) make any outstanding filings required under the Rules, and (b) pay any outstanding fees, assessments, charges, fines, or other amounts due to the Exchange, the Commission, or the Securities Investor Protection Corporation.*

* * * * *

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes amendments to Rule 2.8 (Voluntary Termination of Rights as a Member). Rule 2.8 sets forth the requirements for a Member's voluntary termination of its rights as a Member. Currently, Rule 2.8 provides that a Member's voluntary termination of its rights as a Member shall not take effect until 30 days after all of the following conditions have been satisfied: (i) receipt of such written resignation; (ii) all indebtedness due the Exchange shall have been paid in full; (iii) any Exchange investigation or disciplinary action brought against the Member has reached a final disposition; and (iv) any examination of such Member in process is completed and all exceptions noted have been reasonably resolved. The Rule further provides that the Board may declare a resignation effective at any time.

The Exchange proposes to amend Rule 2.8 to remove conditions set forth in Rule 2.8(iii) and (iv), requiring that any Exchange investigation or disciplinary action brought against the Member has reached a final disposition and that any examination of such Member in process is completed and all exceptions noted have been reasonably resolved. The Exchange further proposes to amend Rule 2.8 to align the voluntary termination rules with that of its affiliates, Cboe Exchange, Inc. (''Cboe Options'') and Cboe C2 Exchange, Inc. (''C2''). Specifically, Cboe Options Rule 3.16 and C2 Rule 3.7 require a terminating Trading Permit Holder to promptly make any outstanding filings required under the respective Rules and pay any outstanding fees, assessments, charges, fines, or other amounts due to each Exchange, the Commission, or the Securities Investor Protection Corporation. The Exchange notes that its affiliates do not maintain a 30-day notice period for terminating members, and now proposes to remove the requirement from the Exchange's Rules. Under Rule 2.8, as amended, the Exchange would require receipt of written resignation, completion of any outstanding filings required under the Rules, and payment of any outstanding fees, assessments, charges, fines, or other amounts due to the Exchange, the Commission, or the Securities Investor Protection Corporation, in order for a Member's voluntary termination of its Member rights to take place.

The Exchange notes that, under Rule 8.1(b), any Member or person associated with a Member shall continue to be subject to the disciplinary jurisdiction of the Exchange following the termination of such person's membership or association with a Member with respect to matters that occurred prior to such termination, provided that written notice of the commencement of an inquiry into such matters is given by the Exchange to such former Member or former associated person within one year of receipt by the Exchange of the latest written notice of the termination of such person's status as a Member or person associated with a Member.[6] Thus, notwithstanding the proposed amendments to Rule 2.8, the Exchange continues to, under Rule 8.1, maintain disciplinary jurisdiction for matters relevant to any in-process examinations or investigations or disciplinary actions brought against a Member that voluntary terminates its membership rights under Rule 2.8, as amended, so long as the Exchange provides written notice to the former Member (or associated person) within one year of receipt of written notice of termination.[7]

As such, the Exchange believes the proposed amendments will not result in any practical changes to the Exchange's disciplinary jurisdiction from an Exchange or Member perspective. Rather, the proposed amendments are designed to facilitate a more efficient voluntary termination process, by allowing Members to terminate their Member status and therefore cease being subject to Member obligations notwithstanding any ongoing disciplinary actions and exams (which may continue for an indeterminate period of time), given the Exchange, via Rule 8.1, maintains jurisdiction over the firm following such termination for disciplinary matters.

Further, the Exchange notes there is no provision under the Securities Exchange Act of 1934 (the ''Act'') which requires that termination be conditioned on final disposition or exam completion. As noted above, the proposed rule change aligns the Exchange's voluntary termination requirements with those of its affiliates, Cboe Options and C2. Under Cboe Options Rule 3.16 (Obligations of Terminating TPHs), each terminating Trading Permit Holder is obligated to promptly (i) return to the Exchange all Exchange badges, including trading and access badges, that were issued to the Trading Permit Holder by the Exchange with respect to that Trading Permit Holder's terminating Trading Permit Holder status, (ii) make any outstanding filings required under Exchange rules, and (iii) pay any outstanding fees, assessments, charges, fines, or other amounts due to the Exchange, the Securities and Exchange Commission, or the Securities Investor Protection Corporation.[8] The Exchange further notes that at least one other exchange has similar obligations for terminating members, in that it does not require that

[6] The notice requirement does not apply to a person who at any time after a termination again subjects himself or herself to the disciplinary jurisdiction of the Exchange by becoming a Member or a person associated with a Member.

[7] For the avoidance of doubt, if a Member voluntarily terminates its membership rights under Rule 2.8, as amended, while an examination or investigation or disciplinary action is in-process, the Exchange will continue to maintain disciplinary jurisdiction over the Member following their termination, subject to the provisions of Rule 8.1.

[8] Cboe Options Rule 3.1(c)(1) requires a Trading Permit Holder seeking to terminate that holder's Trading Permit must notify the Exchange, prior to the deadline announced by the Exchange and in a form and manner prescribed by the Exchange, that the holder is terminating that Trading Permit at the end of its term.

termination be conditioned on final disposition or exam completion.[9]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[10] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [11] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [12] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(1) of the Act,[13] which provides that the Exchange be organized and have the capacity to be able to carry out the purposes of the Act and to enforce compliance by the Exchange's Members and persons associated with its Members with the Act, the rules and regulations thereunder, and the rules of the Exchange.

In particular, the Exchange believes the proposed amendments to the conditional requirements for voluntary termination of Membership will make the termination process more efficient by allowing Members to terminate their Member status and therefore cease being subject to Member obligations notwithstanding any ongoing disciplinary actions and exams (which may continue for an indeterminate period of time), given the Exchange maintains jurisdiction over the firm following such termination for disciplinary matters under Exchange Rules. The Exchange believes the proposed amendments result in a termination process that allows for proper disciplinary jurisdiction while also ensuring that termination is not unduly prolonged due to an administrative technicality within the termination requirements, to the benefit of investors and the public interest. Further, the Exchange believes the proposed changes will serve to avoid wasting Member and Exchange resources on maintaining memberships that are no longer utilized, but unable to be terminated due to ongoing disciplinary action or examination process.

As noted above, the Exchange continues to maintain disciplinary jurisdiction over terminated firms following termination for matters that occurred prior to termination, provided written notice of the commencement of an inquiry into such matters is provided to the terminated Member within one year of the Member's written notice of termination. Therefore, the Exchange believes that the termination requirements set forth in Rule 2.8(iii) and (iv) are unnecessarily duplicative, given the Exchange maintains disciplinary jurisdiction over terminated members via Rule 8.1(b) with respect to matters that occurred prior to such termination, thereby ensuring the Exchange may continue to enforce compliance by the Exchange's Members and persons associated with its Members with the Act, the rules and regulations thereunder, and the rules of the Exchange.

Further, the Exchange believes the proposed rule changes are just, equitable and not unfairly discriminatory because they conform to the process used by its affiliated options exchange, thereby providing consistency across the Cboe family options exchanges in regards to termination requirements. Such consistent requirements may, in turn, simplify the termination process for members of the Exchange that are also participants on Cboe affiliated exchanges. The Exchange believes this consistency will promote a fair and orderly national options market system.

The proposed changes also apply uniformly to all Members that may choose to voluntarily terminate their membership. As noted above, in addition to the Exchange's affiliates, at least one other exchange also has similar termination requirements as those proposed by the Exchange.[14] As such, the proposed rule change would foster cooperation and coordination with persons engaged in facilitating transactions in securities and would remove impediments to and perfect the mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. This proposal does not create an unnecessary or inappropriate intra-market burden on competition because the proposed change will apply uniformly to all Members that choose to voluntarily terminate their membership. Further, the proposed change is not designed to address any competitive issues. Indeed, this proposal does not create an unnecessary or inappropriate inter-market burden on competition because it merely amends the requirements for voluntary termination of rights as a Member and conforms to the requirements of the Exchange's affiliated options exchanges, Cboe Options and C2, as well as at least one other exchange.[15] Finally, as noted above, the Exchange believes the proposed rule amendments will not result in any practical changes to the Exchange's disciplinary jurisdiction from an Exchange or Member perspective, given the Exchange maintains disciplinary jurisdiction over terminated Members following their termination, subject to the provisions of Rule 8.1.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [16] and Rule 19b–4(f)(6) thereunder.[17]

[9] *See* MIAX Options Exchange Rule 206 (Obligations of Terminating Members).

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] *Id.*

[13] 15 U.S.C. 78f(b)(1).

[14] *See supra* note 9. *See also* Cboe Options Rule 3.16 and C2 Rule 3.7.

[15] *Id.*

[16] 15 U.S.C. 78s(b)(3)(A)(iii).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description

Continued

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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–CboeEDGX–2024–018 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–CboeEDGX–2024–018. 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 submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also 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–CboeEDGX–2024–018 and should be submitted on or before April 26, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–07225 Filed 4–4–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99876; File No. SR–CboeEDGA–2024–010]

Self-Regulatory Organizations; Cboe EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 2.8 Regarding Voluntary Termination of Rights as an Exchange Member

April 1, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 19, 2024, Cboe EDGA Exchange, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') proposes to amend Rule 2.8, related to the voluntary termination of rights as an Exchange Member (''Member'').[5] The text of the proposed rule change is provided below.

(additions are *italicized;* deletions are [bracketed])

* * * * *

Rules of Cboe EDGA Exchange, Inc.

* * * * *

Rule 2.8. Voluntary Termination of Rights as a Member

A Member may voluntarily terminate its rights as a Member only by a written resignation addressed to the Exchange's Secretary or another officer designated by the Exchange. [Such resignation shall not take effect until 30 days after all of the following conditions have been satisfied: (i) receipt of such written resignation; (ii) all indebtedness due the Exchange shall have been paid in full; (iii) any Exchange investigation or disciplinary action brought against the Member has reached a final disposition; and (iv) any examination of such Member in process is completed and all exceptions noted have been reasonably resolved; provided, however, that the Board may declare a resignation effective at any time]*Each terminating Member must promptly (a) make any outstanding filings required under the Rules, and (b) pay any outstanding fees, assessments, charges, fines, or other amounts due to the Exchange, the Commission, or the Securities Investor Protection Corporation.*

* * * * *

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/edga/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes amendments to Rule 2.8 (Voluntary Termination of

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.

[18] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* Exchange Rule 1.5(n). The term ''Member'' is defined as ''any registered broker or dealer that has been admitted to membership in the Exchange.''

Rights as a Member). Rule 2.8 sets forth the requirements for a Member's voluntary termination of its rights as a Member. Currently, Rule 2.8 provides that a Member's voluntary termination of its rights as a Member shall not take effect until 30 days after all of the following conditions have been satisfied: (i) receipt of such written resignation; (ii) all indebtedness due the Exchange shall have been paid in full; (iii) any Exchange investigation or disciplinary action brought against the Member has reached a final disposition; and (iv) any examination of such Member in process is completed and all exceptions noted have been reasonably resolved. The Rule further provides that the Board may declare a resignation effective at any time.

The Exchange proposes to amend Rule 2.8 to remove conditions set forth in Rule 2.8(iii) and (iv), requiring that any Exchange investigation or disciplinary action brought against the Member has reached a final disposition and that any examination of such Member in process is completed and all exceptions noted have been reasonably resolved. The Exchange further proposes to amend Rule 2.8 to align the voluntary termination rules with that of its affiliates, Cboe Exchange, Inc. (''Cboe Options'') and Cboe C2 Exchange, Inc. (''C2''). Specifically, Cboe Options Rule 3.16 and C2 Rule 3.7 require a terminating Trading Permit Holder to promptly make any outstanding filings required under the respective Rules and pay any outstanding fees, assessments, charges, fines, or other amounts due to each Exchange, the Commission, or the Securities Investor Protection Corporation. The Exchange notes that its affiliates do not maintain a 30-day notice period for terminating members, and now proposes to remove the requirement from the Exchange's Rules. Under Rule 2.8, as amended, the Exchange would require receipt of written resignation, completion of any outstanding filings required under the Rules, and payment of any outstanding fees, assessments, charges, fines, or other amounts due to the Exchange, the Commission, or the Securities Investor Protection Corporation, in order for a Member's voluntary termination of its Member rights to take place.

The Exchange notes that, under Rule 8.1(b), any Member or person associated with a Member shall continue to be subject to the disciplinary jurisdiction of the Exchange following the termination of such person's membership or association with a Member with respect to matters that occurred prior to such termination, provided that written notice of the commencement of an inquiry into such matters is given by the Exchange to such former Member or former associated person within one year of receipt by the Exchange of the latest written notice of the termination of such person's status as a Member or person associated with a Member.[6] Thus, notwithstanding the proposed amendments to Rule 2.8, the Exchange continues to, under Rule 8.1, maintain disciplinary jurisdiction for matters relevant to any in-process examinations or investigations or disciplinary actions brought against a Member that voluntary terminates its membership rights under Rule 2.8, as amended, so long as the Exchange provides written notice to the former Member (or associated person) within one year of receipt of written notice of termination.[7]

As such, the Exchange believes the proposed amendments will not result in any practical changes to the Exchange's disciplinary jurisdiction from an Exchange or Member perspective. Rather, the proposed amendments are designed to facilitate a more efficient voluntary termination process, by allowing Members to terminate their Member status and therefore cease being subject to Member obligations notwithstanding any ongoing disciplinary actions and exams (which may continue for an indeterminate period of time), given the Exchange, via Rule 8.1, maintains jurisdiction over the firm following such termination for disciplinary matters.

Further, the Exchange notes there is no provision under the Securities Exchange Act of 1934 (the ''Act'') which requires that termination be conditioned on final disposition or exam completion. As noted above, the proposed rule change aligns the Exchange's voluntary termination requirements with those of its affiliates, Cboe Options and C2. Under Cboe Options Rule 3.16 (Obligations of Terminating TPHs), each terminating Trading Permit Holder is obligated to promptly (i) return to the Exchange all Exchange badges, including trading and access badges, that were issued to the Trading Permit Holder by the Exchange with respect to that Trading Permit Holder's terminating Trading Permit Holder status, (ii) make any outstanding filings required under Exchange rules, and (iii) pay any outstanding fees, assessments, charges, fines, or other amounts due to the Exchange, the Securities and Exchange Commission, or the Securities Investor Protection Corporation.[8] The Exchange further notes that at least one other exchange has similar obligations for terminating members, in that it does not require that termination be conditioned on final disposition or exam completion.[9]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[10] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[11] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[12] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(1) of the Act,[13] which provides that the Exchange be organized and have the capacity to be able to carry out the purposes of the Act and to enforce compliance by the Exchange's Members and persons associated with its Members with the Act, the rules and regulations thereunder, and the rules of the Exchange.

In particular, the Exchange believes the proposed amendments to the

[6] The notice requirement does not apply to a person who at any time after a termination again subjects himself or herself to the disciplinary jurisdiction of the Exchange by becoming a Member or a person associated with a Member.

[7] For the avoidance of doubt, if a Member voluntarily terminates its membership rights under Rule 2.8, as amended, while an examination or investigation or disciplinary action is in-process, the Exchange will continue to maintain disciplinary jurisdiction over the Member following their termination, subject to the provisions of Rule 8.1.

[8] Cboe Options Rule 3.1(c)(1) requires a Trading Permit Holder seeking to terminate that holder's Trading Permit must notify the Exchange, prior to the deadline announced by the Exchange and in a form and manner prescribed by the Exchange, that the holder is terminating that Trading Permit at the end of its term.

[9] *See* MIAX Options Exchange Rule 206 (Obligations of Terminating Members).

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] *Id.*

[13] 15 U.S.C. 78f(b)(1).

conditional requirements for voluntary termination of Membership will make the termination process more efficient by allowing Members to terminate their Member status and therefore cease being subject to Member obligations notwithstanding any ongoing disciplinary actions and exams (which may continue for an indeterminate period of time), given the Exchange maintains jurisdiction over the firm following such termination for disciplinary matters under Exchange Rules. The Exchange believes the proposed amendments result in a termination process that allows for proper disciplinary jurisdiction while also ensuring that termination is not unduly prolonged due to an administrative technicality within the termination requirements, to the benefit of investors and the public interest. Further, the Exchange believes the proposed changes will serve to avoid wasting Member and Exchange resources on maintaining memberships that are no longer utilized, but unable to be terminated due to ongoing disciplinary action or examination process.

As noted above, the Exchange continues to maintain disciplinary jurisdiction over terminated firms following termination for matters that occurred prior to termination, provided written notice of the commencement of an inquiry into such matters is provided to the terminated Member within one year of the Member's written notice of termination. Therefore, the Exchange believes that the termination requirements set forth in Rule 2.8(iii) and (iv) are unnecessarily duplicative, given the Exchange maintains disciplinary jurisdiction over terminated members via Rule 8.1(b) with respect to matters that occurred prior to such termination, thereby ensuring the Exchange may continue to enforce compliance by the Exchange's Members and persons associated with its Members with the Act, the rules and regulations thereunder, and the rules of the Exchange.

Further, the Exchange believes the proposed rule changes are just, equitable and not unfairly discriminatory because they conform to the process used by its affiliated options exchange, thereby providing consistency across the Cboe family options exchanges in regards to termination requirements. Such consistent requirements may, in turn, simplify the termination process for members of the Exchange that are also participants on Cboe affiliated exchanges. The Exchange believes this consistency will promote a fair and orderly national options market system.

The proposed changes also apply uniformly to all Members that may choose to voluntarily terminate their membership. As noted above, in addition to the Exchange's affiliates, at least one other exchange also has similar termination requirements as those proposed by the Exchange.[14] As such, the proposed rule change would foster cooperation and coordination with persons engaged in facilitating transactions in securities and would remove impediments to and perfect the mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. This proposal does not create an unnecessary or inappropriate intra-market burden on competition because the proposed change will apply uniformly to all Members that choose to voluntarily terminate their membership. Further, the proposed change is not designed to address any competitive issues. Indeed, this proposal does not create an unnecessary or inappropriate inter-market burden on competition because it merely amends the requirements for voluntary termination of rights as a Member and conforms to the requirements of the Exchange's affiliated options exchanges, Cboe Options and C2, as well as at least one other exchange.[15] Finally, as noted above, the Exchange believes the proposed rule amendments will not result in any practical changes to the Exchange's disciplinary jurisdiction from an Exchange or Member perspective, given the Exchange maintains disciplinary jurisdiction over terminated Members following their termination, subject to the provisions of Rule 8.1.

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.

[14] *See supra* note 9. *See also* Cboe Options Rule 3.16 and C2 Rule 3.7.

[15] *Id.*

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[16] and Rule 19b–4(f)(6) thereunder.[17]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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–CboeEDGA–2024–010 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–CboeEDGA–2024–010. 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 submission, all subsequent amendments, all written statements

[16] 15 U.S.C. 78s(b)(3)(A)(iii).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) 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.

with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also 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–CboeEDGA–2024–010 and should be submitted on or before April 26, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–07224 Filed 4–4–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99874; File No. SR–NYSECHX–2024–14]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.8A and Article 9, Rule 7

April 1, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 25, 2024, the NYSE Chicago, Inc. (''NYSE Chicago'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.8A (Cross Order Settlement Terms) and Article 9, Rule 7 (Transactions ''Ex-Dividend'' and ''Ex-Warrants'') to conform to amendments to Rule 15c6–1(a) of the Act to shorten the standard settlement cycle for most broker-dealer transactions from two business days after the trade date (''T+2'') to one business day after the trade date (''T+1''). The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

On March 6, 2023, the Commission adopted amendments to Rule 15c6–1(a) of the Act to shorten the standard settlement cycle for most broker-dealer transactions from T+2 to T+1.[3] Accordingly, the Exchange proposes to amend Rule 7.8A and Article 9, Rule 7 to conform with the amendments to Rule 15c6–1(a) and reflect a standard settlement cycle of T+1.

Rule 7.8A currently provides that Cross Orders settle ''regular way'' unless designated with one of two ''non-regular way'' settlement terms: Cash or Next Day. A Cross Order designated for ''non-regular way'' settlement may execute at any price without regard to the PBBO or any orders on the Exchange Book. Rule 7.8A defines ''Cash'' settlement as a transaction for delivery on the day of the contract and ''Next Day'' settlement as a transaction for delivery on the next business day following the day of the contract.

Article 9, Rule 7(a) currently provides that transactions in stocks are ex-dividend or ex-rights on the business day immediately preceding the date of record fixed by the corporation for the determination of stockholders entitled to receive such dividends or rights, with certain exceptions. First, as provided in Rule 7(a)(1), when the record date occurs on a holiday or half-holiday, transactions in the stock will be ex-dividend or ex-rights two full business days immediately preceding the record date. Rule 7(a)(2) further provides that ''cash'' transactions are ex-dividend or ex-rights on the day following the record date. Finally, Rule 7(a)(3) provides that the Committee on Exchange Procedure may direct that transactions be ex-dividend or ex-rights on a day other than that fixed by this Rule.

Rule 7(b) currently provides that transactions in securities which have subscription warrants attached, except those made for ''cash,'' will be ex-warrants on the business day preceding the date of expiration of the warrants, with certain exceptions. First, as provided in Rule 7(b)(1), when the day of expiration occurs on a holiday or Sunday, such transactions will be ex-warrants on the second full business day preceding the day of expiration. Rule 7(b)(2) further provides that ''cash'' transactions are ex-warrants on the day following the record date. Finally, Rule 7(b)(c) provides that, notwithstanding the provisions of Rule 7(b) and subparagraphs (1) and (2) thereunder, the Committee on Exchange Procedure may direct otherwise in any specific case.

Proposed Rule Change

To conform Rule 7.8A and Article 9, Rule 7 with the amendments to Rule 15c6–1(a) of the Act adopted by the Commission, the Exchange proposes the following changes:

- The Exchange proposes to amend Rule 7.8A to eliminate Next Day as a ''non-regular way'' settlement option in light of the amendments to Rule 15c6–1(a), because under a T+1 settlement cycle, next day settlement would be considered standard or ''regular way'' settlement.
- The Exchange proposes to amend Rule 7(a) to provide that transactions in stocks, except as provided in the subparagraphs thereunder, will be ex-dividend or ex-rights on the record date, rather than on the business day preceding the record date.

[18] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 96930, 88 FR 13872 (March 6, 2023) (''T+1 Adopting Release'').

• In Rule 7(a)(1), the Exchange proposes to eliminate the reference to a ''half-holiday'' and to amend the Rule to refer to one full business day preceding the record date, rather than two business days.

• The Exchange proposes to amend Rule 7(b) to provide that transactions with subscription warrants attached, except as provided in the subparagraphs thereunder, will be ex-warrants on the date of expiration of the warrants, rather than on the business day preceding such date.

• The Exchange proposes to amend Rule 7(b)(1) to refer to the first full business day preceding the expiration date, rather than the second business day.

Implementation

The Exchange proposes that the operative date of this proposed rule change will be Tuesday, May 28, 2024, which is the compliance date specified in the T+1 Adopting Release, or such later date as may be announced by the Commission for compliance with the amendments to Rule 15c6–1(a) set forth in the T+1 Adopting Release.[4] The Exchange further proposes that, with the implementation of the T+1 settlement cycle and as described in the proposed changes outlined above, the ex-dividend date for ''normal'' distributions will be the same business day as the record date. Accordingly, the Exchange proposes that Wednesday, May 29, 2024 would be the first date to which the proposed rules described herein would apply (*i.e.,* the first record date to which the new ex-dividend date rationale will be applied). During the implementation of the T+1 settlement cycle, the Exchange proposes that the ex-dividend dates will be as follows:

Record date	Ex-dividend date
May 24, 2024	May 23, 2024.
May 28, 2024	May 24, 2024.
May 29, 2024	May 29, 2024.

A record date of Friday, May 24, 2024 would be a date prior to the effective date of the amendments to Rule 15c6–1(a) of the Act to shorten the standard settlement cycle for most broker-dealer transactions from T+2 to T+1.[5] The rules described above would apply to this record date in their current form and, thus, the ''ex-dividend date'' would be the first business day preceding the record date or Thursday, May 23, 2024. Monday, May 27, 2024 is Memorial Day, which is an Exchange holiday; accordingly, there would be no record date on a holiday. A record date of Tuesday, May 28, 2024 would also fall under the Exchange's current rules, and the first business day preceding such record date would be Friday, May 24, 2024. On Wednesday, May 29, 2024, the proposed rules described above would apply, such that, for the record date of May 29, 2024, the ''ex-dividend date'' would be the same business day.

The Exchange will issue a Trader Notice regarding the implementation of the proposed rule change and T+1 settlement cycle, which date would correspond with the industry-led transition to a T+1 standard settlement, and the compliance date of the Commission's amendment of Rule 15c6–1(a) of the Act to require standard settlement no later than T+1.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[6] in general, and furthers the objectives of Section 6(b)(5) of the Act,[7] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, 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 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.

In particular, the proposed rule change would amend the Exchange's rules to reflect a standard settlement cycle of T+1, in support of the industry-led initiative to shorten the settlement cycle to one business day. Moreover, the proposed rule change is consistent with the Commission's amendments to Rule 15c6–1(a) of the Act to require standard settlement no later than T+1. The Exchange believes that the proposed rule change would provide the regulatory certainty to facilitate the industry-led move to a T+1 settlement cycle. Further, the Exchange believes that, by shortening the time period for settlement of most securities transactions, the proposed rule change would protect investors and the public interest by reducing the number of unsettled trades in the clearance and settlement system at any given time, thereby reducing the risk inherent in settling securities transactions to clearing corporations, their members, and public investors.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue, but rather to support the industry's transition to a T+1 regular-way settlement cycle in conformity with the Commission's amendment of Rule 15c6–1(a). The proposed change amends the Exchange's rules pertaining to securities settlement, which rules would apply uniformly to all contracts for the purchase or sale of a security (other than exempted securities) that provide for payment of funds and delivery of securities that occur on the Exchange or other self-regulatory organizations, and is intended to facilitate the industry-wide transition to a T+1 settlement cycle. The Exchange also believes that the proposed rule change will serve to promote clarity and consistency in its rules, thereby reducing burdens on the marketplace and facilitating investor protection. Accordingly, the Exchange believes that the proposed changes do not impose any burden on competition other than that necessary to implement the amendments to Rule 15c6–1(a) of the Act as set forth in the T+1 Adopting Release.[8]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) significantly affect the protection of investors or the public interest;

(ii) impose any significant burden on competition; and

(iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of

[4] *See* note 3, *supra.*

[5] *See* note 3, *supra.*

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] *See* note 3, *supra.*

investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSECHX–2024–14 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–NYSECHX–2024–14. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also 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–NYSECHX–2024–14 and should be submitted on or before April 26, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–07222 Filed 4–4–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99880; File No. SR–CboeBZX–2024–023]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 2.8 Regarding Voluntary Termination of Rights as an Exchange Member

April 1, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 19, 2024, Cboe BZX Exchange, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') proposes to amend Rule 2.8, related to the voluntary termination of rights as an Exchange Member (''Member'').[5] The text of the proposed rule change is provided below.

(Additions are *Italicized;* Deletions are [Bracketed])

* * * * *

Rules of Cboe BZX Exchange, Inc.

* * * * *

Rule 2.8. Voluntary Termination of Rights as a Member

A Member may voluntarily terminate its rights as a Member only by a written resignation addressed to the Exchange's Secretary or another officer designated by the Exchange. [Such resignation shall not take effect until 30 days after all of the following conditions have been satisfied: (i) receipt of such written resignation; (ii) all indebtedness due the Exchange shall have been paid in full; (iii) any Exchange investigation or disciplinary action brought against the Member has reached a final disposition; and (iv) any examination of such Member in process is completed and all exceptions noted have been reasonably resolved; provided, however, that the Board may declare a resignation effective at any time]*Each terminating Member must promptly (a) make any outstanding filings required under the Rules, and (b) pay any outstanding fees, assessments, charges, fines, or other amounts due to the Exchange, the Commission, or the Securities Investor Protection Corporation.*

* * * * *

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes amendments to Rule 2.8 (Voluntary Termination of Rights as a Member). Rule 2.8 sets forth the requirements for a Member's voluntary termination of its rights as a Member. Currently, Rule 2.8 provides that a Member's voluntary termination of its rights as a Member shall not take effect until 30 days after all of the

[9] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* Exchange Rule 1.5(n). The term ''Member'' is defined as ''any registered broker or dealer that has been admitted to membership in the Exchange.''

following conditions have been satisfied: (i) receipt of such written resignation; (ii) all indebtedness due the Exchange shall have been paid in full; (iii) any Exchange investigation or disciplinary action brought against the Member has reached a final disposition; and (iv) any examination of such Member in process is completed and all exceptions noted have been reasonably resolved. The Rule further provides that the Board may declare a resignation effective at any time.

The Exchange proposes to amend Rule 2.8 to remove conditions set forth in Rule 2.8(iii) and (iv), requiring that any Exchange investigation or disciplinary action brought against the Member has reached a final disposition and that any examination of such Member in process is completed and all exceptions noted have been reasonably resolved. The Exchange further proposes to amend Rule 2.8 to align the voluntary termination rules with that of its affiliates, Cboe Exchange, Inc. (''Cboe Options'') and Cboe C2 Exchange, Inc. (''C2''). Specifically, Cboe Options Rule 3.16 and C2 Rule 3.7 require a terminating Trading Permit Holder to promptly make any outstanding filings required under the respective Rules and pay any outstanding fees, assessments, charges, fines, or other amounts due to each Exchange, the Commission, or the Securities Investor Protection Corporation. The Exchange notes that its affiliates do not maintain a 30-day notice period for terminating members, and now proposes to remove the requirement from the Exchange's Rules. Under Rule 2.8, as amended, the Exchange would require receipt of written resignation, completion of any outstanding filings required under the Rules, and payment of any outstanding fees, assessments, charges, fines, or other amounts due to the Exchange, the Commission, or the Securities Investor Protection Corporation, in order for a Member's voluntary termination of its Member rights to take place.

The Exchange notes that, under Rule 8.1(b), any Member or person associated with a Member shall continue to be subject to the disciplinary jurisdiction of the Exchange following the termination of such person's membership or association with a Member with respect to matters that occurred prior to such termination, provided that written notice of the commencement of an inquiry into such matters is given by the Exchange to such former Member or former associated person within one year of receipt by the Exchange of the latest written notice of the termination of such person's status as a Member or person associated with a Member.[6] Thus, notwithstanding the proposed amendments to Rule 2.8, the Exchange continues to, under Rule 8.1, maintain disciplinary jurisdiction for matters relevant to any in-process examinations or investigations or disciplinary actions brought against a Member that voluntary terminates its membership rights under Rule 2.8, as amended, so long as the Exchange provides written notice to the former Member (or associated person) within one year of receipt of written notice of termination.[7]

As such, the Exchange believes the proposed amendments will not result in any practical changes to the Exchange's disciplinary jurisdiction from an Exchange or Member perspective. Rather, the proposed amendments are designed to facilitate a more efficient voluntary termination process, by allowing Members to terminate their Member status and therefore cease being subject to Member obligations notwithstanding any ongoing disciplinary actions and exams (which may continue for an indeterminate period of time), given the Exchange, via Rule 8.1, maintains jurisdiction over the firm following such termination for disciplinary matters.

Further, the Exchange notes there is no provision under the Securities Exchange Act of 1934 (the ''Act'') which requires that termination be conditioned on final disposition or exam completion. As noted above, the proposed rule change aligns the Exchange's voluntary termination requirements with those of its affiliates, Cboe Options and C2. Under Cboe Options Rule 3.16 (Obligations of Terminating TPHs), each terminating Trading Permit Holder is obligated to promptly (i) return to the Exchange all Exchange badges, including trading and access badges, that were issued to the Trading Permit Holder by the Exchange with respect to that Trading Permit Holder's terminating Trading Permit Holder status, (ii) make any outstanding filings required under Exchange rules, and (iii) pay any outstanding fees, assessments, charges, fines, or other amounts due to the Exchange, the Securities and Exchange Commission, or the Securities Investor Protection Corporation.[8] The Exchange further notes that at least one other exchange has similar obligations for terminating members, in that it does not require that termination be conditioned on final disposition or exam completion.[9]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[10] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [11] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [12] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(1) of the Act,[13] which provides that the Exchange be organized and have the capacity to be able to carry out the purposes of the Act and to enforce compliance by the Exchange's Members and persons associated with its Members with the Act, the rules and regulations thereunder, and the rules of the Exchange.

In particular, the Exchange believes the proposed amendments to the conditional requirements for voluntary termination of Membership will make the termination process more efficient by allowing Members to terminate their Member status and therefore cease being subject to Member obligations notwithstanding any ongoing

[6] The notice requirement does not apply to a person who at any time after a termination again subjects himself or herself to the disciplinary jurisdiction of the Exchange by becoming a Member or a person associated with a Member.

[7] For the avoidance of doubt, if a Member voluntarily terminates its membership rights under Rule 2.8, as amended, while an examination or investigation or disciplinary action is in-process, the Exchange will continue to maintain disciplinary jurisdiction over the Member following their termination, subject to the provisions of Rule 8.1.

[8] Cboe Options Rule 3.1(c)(1) requires a Trading Permit Holder seeking to terminate that holder's Trading Permit must notify the Exchange, prior to the deadline announced by the Exchange and in a form and manner prescribed by the Exchange, that the holder is terminating that Trading Permit at the end of its term.

[9] *See* MIAX Options Exchange Rule 206 (Obligations of Terminating Members).

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] *Id.*

[13] 15 U.S.C. 78f(b)(1).

disciplinary actions and exams (which may continue for an indeterminate period of time), given the Exchange maintains jurisdiction over the firm following such termination for disciplinary matters under Exchange Rules. The Exchange believes the proposed amendments result in a termination process that allows for proper disciplinary jurisdiction while also ensuring that termination is not unduly prolonged due to an administrative technicality within the termination requirements, to the benefit of investors and the public interest. Further, the Exchange believes the proposed changes will serve to avoid wasting Member and Exchange resources on maintaining memberships that are no longer utilized, but unable to be terminated due to ongoing disciplinary action or examination process.

As noted above, the Exchange continues to maintain disciplinary jurisdiction over terminated firms following termination for matters that occurred prior to termination, provided written notice of the commencement of an inquiry into such matters is provided to the terminated Member within one year of the Member's written notice of termination. Therefore, the Exchange believes that the termination requirements set forth in Rule 2.8(iii) and (iv) are unnecessarily duplicative, given the Exchange maintains disciplinary jurisdiction over terminated members via Rule 8.1(b) with respect to matters that occurred prior to such termination, thereby ensuring the Exchange may continue to enforce compliance by the Exchange's Members and persons associated with its Members with the Act, the rules and regulations thereunder, and the rules of the Exchange.

Further, the Exchange believes the proposed rule changes are just, equitable and not unfairly discriminatory because they conform to the process used by its affiliated options exchange, thereby providing consistency across the Cboe family options exchanges in regards to termination requirements. Such consistent requirements may, in turn, simplify the termination process for members of the Exchange that are also participants on Cboe affiliated exchanges. The Exchange believes this consistency will promote a fair and orderly national options market system.

The proposed changes also apply uniformly to all Members that may choose to voluntarily terminate their membership. As noted above, in addition to the Exchange's affiliates, at least one other exchange also has similar termination requirements as those proposed by the Exchange.[14] As such, the proposed rule change would foster cooperation and coordination with persons engaged in facilitating transactions in securities and would remove impediments to and perfect the mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. This proposal does not create an unnecessary or inappropriate intra-market burden on competition because the proposed change will apply uniformly to all Members that choose to voluntarily terminate their membership. Further, the proposed change is not designed to address any competitive issues. Indeed, this proposal does not create an unnecessary or inappropriate inter-market burden on competition because it merely amends the requirements for voluntary termination of rights as a Member and conforms to the requirements of the Exchange's affiliated options exchanges, Cboe Options and C2, as well as at least one other exchange.[15] Finally, as noted above, the Exchange believes the proposed rule amendments will not result in any practical changes to the Exchange's disciplinary jurisdiction from an Exchange or Member perspective, given the Exchange maintains disciplinary jurisdiction over terminated Members following their termination, subject to the provisions of Rule 8.1.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[16] and Rule 19b–4(f)(6) thereunder.[17]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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–CboeBZX–2024–023 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–CboeBZX–2024–023. 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 submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official

[14] *See supra* note 9. *See also* Cboe Options Rule 3.16 and C2 Rule 3.7.

[15] *Id.*

[16] 15 U.S.C. 78s(b)(3)(A)(iii).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) 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.

business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also 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–CboeBZX–2024–023 and should be submitted on or before April 26, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–07217 Filed 4–4–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99871; File No. SR–NYSE–2024–19]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Dealings and Settlements, Rule 235, and Rule 236, Sections 204.12, 703.02, and 703.03 of the Listed Company Manual

April 1, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 25, 2024, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Dealings and Settlements, Rule 235, and Rule 236, as well as Sections 204.12, 703.02 (part 2), and 703.03 of the Listed Company Manual, to conform to amendments to Rule 15c6–1(a) of the Act to shorten the standard settlement cycle for most broker-dealer transactions from two business days after the trade date (''T+2'') to one business day after the trade date (''T+1''). The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

On March 6, 2023, the Commission adopted amendments to Rule 15c6–1(a) of the Act to shorten the standard settlement cycle for most broker-dealer transactions from T+2 to T+1.[3] Accordingly, the Exchange proposes to amend the rules identified below to conform with the amendments to Rule 15c6–1(a) and reflect a standard settlement cycle of T+1:

- Dealings and Settlements
- Rule 235 (Ex-Dividend, Ex-Rights)
- Rule 236 (Ex-Warrants)
- Section 204.12 of the Listed Company Manual (Dividends and Stock Distributions)
- Section 703.02 (part 2) of the Listed Company Manual (Stock Split/Stock Rights/Stock Dividend Listing Process)
- Section 703.03 of the Listed Company Manual (Short Term Rights Offerings Relating to Listed Securities Listing Process)

Proposed Rule Change

The Exchange proposes the following changes to reflect a T+1 settlement cycle.

- Under Dealings and Settlements, Delivery Dates on Exchange Contracts currently provides that a ''Regular Way'' contract for sale of securities is due on the second business day following the day of the contract. The Exchange proposes to delete the word ''second'' from this rule to reflect settlement on T+1, rather than T+2.[4]
- Current Rule 235 provides that transactions in stocks shall be ex-dividend or ex-rights on the business day preceding the record date fixed by the corporation or the date of the closing of transfer books. The Exchange proposes to delete the phrase ''the business day preceding,'' such that the rule would provide that these transactions would be ex-dividend or ex-rights on the record date. The current rule further provides that if the record date or closing of transfer books occurs upon a day other than a business day, Rule 235 shall apply for the second preceding business day. The Exchange proposes to delete the word ''second'' from this portion of the rule to conform to a T+1 settlement cycle.[5]
- Current Rule 236 provides that ex-warrant trading will begin on the business day preceding the date of expiration of the warrants, expect that when expiration occurs on a non-business day, it will begin on the second business day preceding expiration. To conform with a T+1 settlement cycle, the Exchange proposes to delete the phrase ''the business day preceding,'' such that the rule would provide that these transactions would be ex-warrants on the date of expiration, and the word ''second,'' such that the rule would provide for expiration on the business day preceding expiration when expiration occurs on a non-business day.
- Current Section 204.12 of the Listed Company Manual (Dividends and Stock Distributions) requires the Exchange to arrange for and give advance notice of changes in dealings in the stock to an ''ex-dividend'' basis, which is generally

[18] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 96930, 88 FR 13872 (March 6, 2023) (''T+1 Adopting Release'').

[4] The Exchange further proposes to modify the table that appears under Delivery Dates on Exchange Contracts to delete the rows describing ''Cash'' delivery and ''Seller's Option'' delivery, as the Exchange discontinued non-regular way settlement in 2017 and such options are no longer offered. *See* Securities Exchange Act Release No. 81176 (July 20, 2017), 82 FR 34728 (July 26, 2017) (SR–NYSE–2017–33) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Eliminate Non-Regular Way Trading on the Exchange).

[5] The Exchange further proposes to delete the parenthetical sentence at the end of Rule 235 as obsolete, given that Rule 118 has been deleted from the Exchange's rulebook. *See* Securities Exchange Act Release No. 76649 (December 15, 2015), 80 FR 79365 (December 21, 2015) (SR–NYSE–2015–60) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 13 To Eliminate Good til Cancelled (''GTC'') Orders and Stop Orders, and Make Conforming Changes to Rules 49, 61, 70, 104, 109, 115A, 116, 118, 123, 123A, 123C, 123D, 1000, 1004 and 6140).

two business days prior to the record date. The Exchange proposes to amend Section 204.12 to provide that an ''ex-dividend'' basis would generally be on the record date to reflect a T+1 settlement cycle.

• Current Section 703.02 (part 2) of the Listed Company Manual (Stock Split/Stock Rights/Stock Dividend Listing Process) provides that a distribution of less than 25% of a company's common stock is traded ''ex'' on and after the business day prior to the record date based on the Exchange's two-day delivery rule, pursuant to which contracts made on the Exchange for the purchase and sale of securities are generally settled by delivery on the second business day after the contract is made. Given the change to a T+1 settlement cycle, the Exchange proposes to amend the first sentence of Section 703.02 (part 2) to reflect that a distribution of less than 25% of a company's common stock is traded ''ex'' on the record date. The Exchange also proposes to amend the second sentence of Section 703.02 (part 2) to instead refer to the Exchange's one-day delivery rule pursuant to which contracts made on the Exchange for the purchase and sale of securities are settled by delivery on the business day after the contract is made. Finally, the Exchange proposes to amend the table in Section 703.02 (part 2) setting forth a schedule of record dates and corresponding normal ex-dividend dates to reflect a shortened T+1 settlement cycle.[6]

• Current Section 703.03 of the Listed Company Manual (Short Term Rights Offerings Relating to Listed Securities Listing Process) provides that registration under the Securities Act of 1933 of securities to be offered should become effective at least six business days prior to the record date so that a listed security may trade ex-rights in a normal fashion on the second business day prior to the record date. The Exchange proposes to amend Section 703.03 to provide that registration of listed securities should become effective at least six business days prior to the record date in order for such securities to be traded ex-rights on the record date.

[6] The Exchange also proposes to add Juneteenth National Independence Day (June 19) to the list of holidays affecting ex-dividend dates set forth in Section 703.02 (part 2). This proposed change would ensure that Section 703.02 is consistent with NYSE Rule 7.2, which sets forth the holidays on which the Exchange is not open for business and was amended in 2021 to include Juneteenth National Independence Day. *See* Securities Exchange Act Release No. 93183 (September 30, 2021), 86 FR 55068 (October 5, 2021) (SR–NYSE–2021–56) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend NYSE Rule 7.2).

Implementation

The Exchange proposes that the operative date of this proposed rule change will be Tuesday, May 28, 2024, which is the compliance date specified in the T+1 Adopting Release, or such later date as may be announced by the Commission for compliance with the amendments to Rule 15c6–1(a) set forth in the T+1 Adopting Release.[7] With the implementation of the T+1 settlement cycle and as described in the proposed changes outlined above, the ex-dividend date for ''normal'' distributions will be the same business day as the record date. Accordingly, the Exchange proposes that Wednesday, May 29, 2024 would be the first date to which the proposed rules described herein would apply (*i.e.,* the first record date to which the new ex-dividend date rationale will be applied). During the implementation of the T+1 settlement cycle, the Exchange proposes that the ex-dividend dates will be as follows:

Record date	Ex-dividend date
May 24, 2024	May 23, 2024.
May 28, 2024	May 24, 2024.
May 29, 2024	May 29, 2024.

A record date of Friday, May 24, 2024 would be a date prior to the effective date of the amendments to Rule 15c6–1(a) of the Act to shorten the standard settlement cycle for most broker-dealer transactions from T+2 to T+1.[8] The rules described above would apply to this record date in their current form and, thus, the ''ex-dividend date'' would be the first business day preceding the record date or Thursday, May 23, 2024. Monday, May 27, 2024 is Memorial Day, which is an Exchange holiday; accordingly, there would be no record date on a holiday. A record date of Tuesday, May 28, 2024 would also fall under the Exchange's current rules, and the first business day preceding such record date would be Friday, May 24, 2024. On Wednesday, May 29, 2024, the proposed rules described above would apply, such that, for the record date of May 29, 2024, the ''ex-dividend date'' would be the same business day.

The Exchange will issue a Trader Notice regarding the implementation of the proposed rule change and T+1 settlement cycle, which date would correspond with the industry-led transition to a T+1 standard settlement, and the compliance date of the Commission's amendment of Rule 15c6–1(a) of the Act to require standard settlement no later than T+1.

[7] *See* note 3, *supra.*

[8] *See* note 3, *supra.*

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, 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 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.

In particular, the proposed rule change would amend the Exchange's rules to reflect a standard settlement cycle of T+1, in support of the industry-led initiative to shorten the settlement cycle to one business day. Moreover, the proposed rule change is consistent with the Commission's amendments to Rule 15c6–1(a) of the Act to require standard settlement no later than T+1. The Exchange believes that the proposed rule change would provide regulatory certainty to facilitate the industry-led move to a T+1 settlement cycle. The Exchange further believes that, by shortening the time period for settlement of most securities transactions, the proposed rule change would protect investors and the public interest by reducing the number of unsettled trades in the clearance and settlement system at any given time, thereby reducing the risk inherent in settling securities transactions to clearing corporations, their members, and public investors.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue, but rather to support the industry's transition to a T+1 regular-way settlement cycle in conformity with the Commission's amendment of Rule 15c6–1(a). The proposed change amends the Exchange's rules pertaining to securities settlement, which rules would apply uniformly to all contracts for the purchase or sale of a security (other than exempted securities) that provide for payment of funds and delivery of securities that occur on the Exchange or

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

other self-regulatory organizations, and is intended to facilitate the industry-wide transition to a T+1 settlement cycle. The Exchange also believes that the proposed rule change will serve to promote clarity and consistency in its rules, thereby reducing burdens on the marketplace and facilitating investor protection. Accordingly, the Exchange believes that the proposed changes do not impose any burden on competition other than that necessary to implement the amendments to Rule 15c6–1(a) of the Act as set forth in the T+1 Adopting Release.[11]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) significantly affect the protection of investors or the public interest;

(ii) impose any significant burden on competition; and

(iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSE–2024–19 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSE–2024–19. 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 submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also 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–NYSE–2024–19 and should be submitted on or before April 26, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–07219 Filed 4–4–24; 8:45 am]

BILLING CODE 8011–01–P

[11] *See* note 3, *supra.*

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99873; File No. SR–NYSENAT–2024–12]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.4

April 1, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 25, 2024, NYSE National, Inc. (''NYSE National'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.4 (Ex-Dividend or Ex-Right Dates) to conform to amendments to Rule 15c6–1(a) of the Act to shorten the standard settlement cycle for most broker-dealer transactions from two business days after the trade date (''T+2'') to one business day after the trade date (''T+1''). The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

On March 6, 2023, the Commission adopted amendments to Rule 15c6–1(a) of the Act to shorten the standard settlement cycle for most broker-dealer transactions from T+2 to T+1.[3] Accordingly, the Exchange proposes to amend Rule 7.4 to conform with the amendments to Rule 15c6–1(a) and reflect a standard settlement cycle of T+1.

Rule 7.4 currently provides that transactions in stocks traded ''regular way'' are generally ''ex-dividend'' or ''ex-rights'' on the business day preceding the record date fixed by the company or the date of the closing of transfer books. The rule further provides that, if the record date or closing of transfer books occur on a day other than a business day, transactions would be ''ex-dividend'' or ''ex-rights'' on the second preceding business day.

The Exchange proposes to amend Rule 7.4 to provide, in conformity with the transition to a T+1 settlement cycle, that transactions in stocks traded ''regular way'' will be ''ex-dividend'' or ''ex-rights'' on the record date fixed by the company or the date of the closing of transfer books, or if the record date or closing of transfer books occur on a day other than a business day, on the preceding business day.

Implementation

The Exchange proposes that the operative date of this proposed rule change will be Tuesday, May 28, 2024, which is the compliance date specified in the T+1 Adopting Release, or such later date as may be announced by the Commission for compliance with the amendments to Rule 15c6–1(a) set forth in the T+1 Adopting Release.[4] With the implementation of the T+1 settlement cycle and as described in the proposed changes outlined above, the ex-dividend date for ''normal'' distributions will be the same business day as the record date. Accordingly, the Exchange proposes that Wednesday, May 29, 2024 would be the first date to which the proposed rules described herein would apply (*i.e.,* the first record date to which the new ex-dividend date rationale will be applied). During the implementation of the T+1 settlement cycle, the Exchange proposes that the ex-dividend dates will be as follows:

Record date	Ex-dividend date
May 24, 2024	May 23, 2024.
May 28, 2024	May 24, 2024.
May 29, 2024	May 29, 2024.

A record date of Friday, May 24, 2024 would be a date prior to the effective date of the amendments to Rule 15c6–1(a) of the Act to shorten the standard settlement cycle for most broker-dealer transactions from T+2 to T+1.[5] The rules described above would apply to this record date in their current form and, thus, the ''ex-dividend date'' would be the first business day preceding the record date or Thursday, May 23, 2024. Monday, May 27, 2024 is Memorial Day, which is an Exchange holiday; accordingly, there would be no record date on a holiday. A record date of Tuesday, May 28, 2024 would also fall under the Exchange's current rules, and the first business day preceding such record date would be Friday, May 24, 2024. On Wednesday, May 29, 2024, the proposed rules described above would apply, such that, for the record date of May 29, 2024, the ''ex-dividend date'' would be the same business day.

The Exchange will issue a Trader Notice regarding the implementation of the proposed rule change and T+1 settlement cycle, which date would correspond with the industry-led transition to a T+1 standard settlement, and the compliance date of the Commission's amendment of Rule 15c6–1(a) of the Act to require standard settlement no later than T+1.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[6] in general, and furthers the objectives of Section 6(b)(5) of the Act,[7] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, 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 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.

In particular, the proposed rule change would amend the Exchange's rules to reflect a standard settlement cycle of T+1, in support of the industry-led initiative to shorten the settlement cycle to one business day. Moreover, the proposed rule change is consistent with the Commission's amendments to Rule 15c6–1(a) of the Act to require standard settlement no later than T+1. The Exchange believes that the proposed rule change would provide regulatory certainty to facilitate the industry-led move to a T+1 settlement cycle. The Exchange further believes that, by shortening the time period for settlement of most securities transactions, the proposed rule change would protect investors and the public interest by reducing the number of unsettled trades in the clearance and settlement system at any given time, thereby reducing the risk inherent in settling securities transactions to clearing corporations, their members, and public investors.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue, but rather to support the industry's transition to a T+1 regular-way settlement cycle in conformity with the Commission's amendment of Rule 15c6–1(a). The proposed change amends the Exchange's rules pertaining to securities settlement, which rules would apply uniformly to all contracts for the purchase or sale of a security (other than exempted securities) that provide for payment of funds and delivery of securities that occur on the Exchange or other self-regulatory organizations, and is intended to facilitate the industry-wide transition to a T+1 settlement cycle. The Exchange also believes that the proposed rule change will serve to promote clarity and consistency in its rules, thereby reducing burdens on the marketplace and facilitating investor protection. Accordingly, the Exchange believes that the proposed changes do not impose any burden on competition other than that necessary to implement the amendments to Rule 15c6–1(a) of the Act as set forth in the T+1 Adopting Release.[8]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

[3] *See* Securities Exchange Act Release No. 96930, 88 FR 13872 (March 6, 2023) (''T+1 Adopting Release'').

[4] *See id.*

[5] *See* note 3, *supra.*

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] *See* note 3, *supra.*

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) significantly affect the protection of investors or the public interest;

(ii) impose any significant burden on competition; and

(iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSENAT–2024–12 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSENAT–2024–12. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also 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–NYSENAT–2024–12 and should be submitted on or before April 26, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–07221 Filed 4–4–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–663, OMB Control No. 3235–0724]

Submission for OMB Review; Comment Request; Extension: Supplier Diversity Business Management System

Upon Written Request Copies Available From: U.S. 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 (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information discussed below.

The Commission is required under section 342 of the Dodd-Frank Wall Street and Reform Act to develop standards and processes for ensuring the fair inclusion of women-owned and minority-owned businesses in all of the Commission's business activities. In addition, the Commission is required to develop standards for coordinating technical assistance to minority-owned and women-owned businesses. 12 U.S.C. 5452(b)(2)(B). To help implement these requirements, the Office of Minority and Women Inclusion (OMWI) developed and maintains an electronic Supplier Diversity Business Management System (SDBMS) to collect up-to-date business information and capabilities statements from diverse suppliers interested in doing business with the Commission. The information collected in SDBMS assists the Commission with its market research efforts, enables the Commission to assess the effectiveness of its technical assistance and outreach efforts and identify target areas for additional program efforts, and facilitates the Commission's compliance with its Congressionally-mandated reporting obligations on the Commission's contract awards.

The Commission invited comments on SDBMS. Information is collected in SDBMS via web-based, e-filed, dynamic form-based technology. The company point of contact completes a profile consisting of basic contact data and information on the capabilities of the business. The profile includes a series of questions, some of which are based on the data that the individual enters. Drop-down lists are included where appropriate to increase ease of use.

The information collection is voluntary. There are no costs associated with this collection. SDBMS allows suppliers to self-register via a secure web portal that is accessible through a hyperlink on the Commission's public website.

Title of Collection: Supplier Diversity Management System.

Type of Review: Request for extension of previously approved collection of information.

Estimated Number of Annual Responses: 300.

Estimated Annual Reporting Burden: 150 hours (30 minutes per submission).

On February 1, 2024, the Commission published a notice in the **Federal Register** (89 FR 6558) of its intention to request an extension of this currently approved collection of information and allowed the public 60 days to submit comments. The Commission received no comments.

Written comments continue to be invited on: (a) whether this collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection

[9] 17 CFR 200.30–3(a)(12).

techniques or other forms of information technology.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent by May 6, 2024 to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov*.

Dated: April 1, 2024.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–07208 Filed 4–4–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99878; File No. SR–CboeBYX–2024–008]

Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 2.8 Regarding Voluntary Termination of Rights as an Exchange Member

April 1, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 19, 2024, Cboe BYX Exchange, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal pursuant to Section 19(b)(3)(A)(iii) of the Act [3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BYX Exchange, Inc. (the ''Exchange'' or ''BYX'') proposes to amend Rule 2.8, related to the voluntary termination of rights as an Exchange Member (''Member'').[5] The text of the proposed rule change is provided below.

(additions are *italicized;* deletions are [bracketed])

* * * * *

Rules of Cboe BYX Exchange, Inc.

* * * * *

Rule 2.8. Voluntary Termination of Rights as a Member

A Member may voluntarily terminate its rights as a Member only by a written resignation addressed to the Exchange's Secretary or another officer designated by the Exchange. [Such resignation shall not take effect until 30 days after all of the following conditions have been satisfied: (i) receipt of such written resignation; (ii) all indebtedness due the Exchange shall have been paid in full; (iii) any Exchange investigation or disciplinary action brought against the Member has reached a final disposition; and (iv) any examination of such Member in process is completed and all exceptions noted have been reasonably resolved; provided, however, that the Board may declare a resignation effective at any time]*Each terminating Member must promptly (a) make any outstanding filings required under the Rules, and (b) pay any outstanding fees, assessments, charges, fines, or other amounts due to the Exchange, the Commission, or the Securities Investor Protection Corporation.*

* * * * *

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/byx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes amendments to Rule 2.8 (Voluntary Termination of Rights as a Member). Rule 2.8 sets forth the requirements for a Member's voluntary termination of its rights as a Member. Currently, Rule 2.8 provides that a Member's voluntary termination of its rights as a Member shall not take effect until 30 days after all of the following conditions have been satisfied: (i) receipt of such written resignation; (ii) all indebtedness due the Exchange shall have been paid in full; (iii) any Exchange investigation or disciplinary action brought against the Member has reached a final disposition; and (iv) any examination of such Member in process is completed and all exceptions noted have been reasonably resolved. The Rule further provides that the Board may declare a resignation effective at any time.

The Exchange proposes to amend Rule 2.8 to remove conditions set forth in Rule 2.8(iii) and (iv), requiring that any Exchange investigation or disciplinary action brought against the Member has reached a final disposition and that any examination of such Member in process is completed and all exceptions noted have been reasonably resolved. The Exchange further proposes to amend Rule 2.8 to align the voluntary termination rules with that of its affiliates, Cboe Exchange, Inc. (''Cboe Options'') and Cboe C2 Exchange, Inc. (''C2''). Specifically, Cboe Options Rule 3.16 and C2 Rule 3.7 require a terminating Trading Permit Holder to promptly make any outstanding filings required under the respective Rules and pay any outstanding fees, assessments, charges, fines, or other amounts due to each Exchange, the Commission, or the Securities Investor Protection Corporation. The Exchange notes that its affiliates do not maintain a 30-day notice period for terminating members, and now proposes to remove the requirement from the Exchange's Rules. Under Rule 2.8, as amended, the Exchange would require receipt of written resignation, completion of any outstanding filings required under the Rules, and payment of any outstanding fees, assessments, charges, fines, or

[5] *See* Exchange Rule 1.5(n). The term ''Member'' is defined as ''any registered broker or dealer that has been admitted to membership in the Exchange.''

other amounts due to the Exchange, the Commission, or the Securities Investor Protection Corporation, in order for a Member's voluntary termination of its Member rights to take place.

The Exchange notes that, under Rule 8.1(b), any Member or person associated with a Member shall continue to be subject to the disciplinary jurisdiction of the Exchange following the termination of such person's membership or association with a Member with respect to matters that occurred prior to such termination, provided that written notice of the commencement of an inquiry into such matters is given by the Exchange to such former Member or former associated person within one year of receipt by the Exchange of the latest written notice of the termination of such person's status as a Member or person associated with a Member.[6] Thus, notwithstanding the proposed amendments to Rule 2.8, the Exchange continues to, under Rule 8.1, maintain disciplinary jurisdiction for matters relevant to any in-process examinations or investigations or disciplinary actions brought against a Member that voluntary terminates its membership rights under Rule 2.8, as amended, so long as the Exchange provides written notice to the former Member (or associated person) within one year of receipt of written notice of termination.[7]

As such, the Exchange believes the proposed amendments will not result in any practical changes to the Exchange's disciplinary jurisdiction from an Exchange or Member perspective. Rather, the proposed amendments are designed to facilitate a more efficient voluntary termination process, by allowing Members to terminate their Member status and therefore cease being subject to Member obligations notwithstanding any ongoing disciplinary actions and exams (which may continue for an indeterminate period of time), given the Exchange, via Rule 8.1, maintains jurisdiction over the firm following such termination for disciplinary matters.

Further, the Exchange notes there is no provision under the Securities Exchange Act of 1934 (the ''Act'') which requires that termination be conditioned on final disposition or exam completion. As noted above, the proposed rule change aligns the Exchange's voluntary termination requirements with those of its affiliates, Cboe Options and C2. Under Cboe Options Rule 3.16 (Obligations of Terminating TPHs), each terminating Trading Permit Holder is obligated to promptly (i) return to the Exchange all Exchange badges, including trading and access badges, that were issued to the Trading Permit Holder by the Exchange with respect to that Trading Permit Holder's terminating Trading Permit Holder status, (ii) make any outstanding filings required under Exchange rules, and (iii) pay any outstanding fees, assessments, charges, fines, or other amounts due to the Exchange, the Securities and Exchange Commission, or the Securities Investor Protection Corporation.[8] The Exchange further notes that at least one other exchange has similar obligations for terminating members, in that it does not require that termination be conditioned on final disposition or exam completion.[9]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[10] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [11] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [12] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(1) of the Act,[13] which provides that the Exchange be organized and have the capacity to be able to carry out the purposes of the Act and to enforce compliance by the Exchange's Members and persons associated with its Members with the Act, the rules and regulations thereunder, and the rules of the Exchange.

In particular, the Exchange believes the proposed amendments to the conditional requirements for voluntary termination of Membership will make the termination process more efficient by allowing Members to terminate their Member status and therefore cease being subject to Member obligations notwithstanding any ongoing disciplinary actions and exams (which may continue for an indeterminate period of time), given the Exchange maintains jurisdiction over the firm following such termination for disciplinary matters under Exchange Rules. The Exchange believes the proposed amendments result in a termination process that allows for proper disciplinary jurisdiction while also ensuring that termination is not unduly prolonged due to an administrative technicality within the termination requirements, to the benefit of investors and the public interest. Further, the Exchange believes the proposed changes will serve to avoid wasting Member and Exchange resources on maintaining memberships that are no longer utilized, but unable to be terminated due to ongoing disciplinary action or examination process.

As noted above, the Exchange continues to maintain disciplinary jurisdiction over terminated firms following termination for matters that occurred prior to termination, provided written notice of the commencement of an inquiry into such matters is provided to the terminated Member within one year of the Member's written notice of termination. Therefore, the Exchange believes that the termination requirements set forth in Rule 2.8(iii) and (iv) are unnecessarily duplicative, given the Exchange maintains disciplinary jurisdiction over terminated members via Rule 8.1(b) with respect to matters that occurred prior to such termination, thereby ensuring the Exchange may continue to enforce compliance by the Exchange's Members and persons associated with its Members with the Act, the rules and

[6] The notice requirement does not apply to a person who at any time after a termination again subjects himself or herself to the disciplinary jurisdiction of the Exchange by becoming a Member or a person associated with a Member.

[7] For the avoidance of doubt, if a Member voluntarily terminates its membership rights under Rule 2.8, as amended, while an examination or investigation or disciplinary action is in-process, the Exchange will continue to maintain disciplinary jurisdiction over the Member following their termination, subject to the provisions of Rule 8.1.

[8] Cboe Options Rule 3.1(c)(1) requires a Trading Permit Holder seeking to terminate that holder's Trading Permit must notify the Exchange, prior to the deadline announced by the Exchange and in a form and manner prescribed by the Exchange, that the holder is terminating that Trading Permit at the end of its term.

[9] *See* MIAX Options Exchange Rule 206 (Obligations of Terminating Members).

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] *Id.*

[13] 15 U.S.C. 78f(b)(1).

regulations thereunder, and the rules of the Exchange.

Further, the Exchange believes the proposed rule changes are just, equitable and not unfairly discriminatory because they conform to the process used by its affiliated options exchange, thereby providing consistency across the Cboe family options exchanges in regards to termination requirements. Such consistent requirements may, in turn, simplify the termination process for members of the Exchange that are also participants on Cboe affiliated exchanges. The Exchange believes this consistency will promote a fair and orderly national options market system.

The proposed changes also apply uniformly to all Members that may choose to voluntarily terminate their membership. As noted above, in addition to the Exchange's affiliates, at least one other exchange also has similar termination requirements as those proposed by the Exchange.[14] As such, the proposed rule change would foster cooperation and coordination with persons engaged in facilitating transactions in securities and would remove impediments to and perfect the mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. This proposal does not create an unnecessary or inappropriate intra-market burden on competition because the proposed change will apply uniformly to all Members that choose to voluntarily terminate their membership. Further, the proposed change is not designed to address any competitive issues. Indeed, this proposal does not create an unnecessary or inappropriate inter-market burden on competition because it merely amends the requirements for voluntary termination of rights as a Member and conforms to the requirements of the Exchange's affiliated options exchanges, Cboe Options and C2, as well as at least one other exchange.[15] Finally, as noted above, the Exchange believes the proposed rule amendments will not result in any practical changes to the Exchange's disciplinary jurisdiction from an Exchange or Member perspective, given the Exchange maintains disciplinary jurisdiction over terminated Members following their termination, subject to the provisions of Rule 8.1.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[16] and Rule 19b–4(f)(6) thereunder.[17]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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–CboeBYX–2024–008 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–CboeBYX–2024–008. 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 submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also 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–CboeBYX–2024–008 and should be submitted on or before April 26, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

J. Matthew DeLesDernier,

Deputy Secretary.

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[14] *See supra* note 9. *See also* Cboe Options Rule 3.16 and C2 Rule 3.7.

[15] *Id.*

[16] 15 U.S.C. 78s(b)(3)(A)(iii).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) 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.

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99879; File No. SR–NASDAQ–2024–016]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Encourage Members To Contribute Liquidity to the Exchange by Offering Those That Maintain a Particular Minimum Trading Volume Lower Fees for Specified Market Data and Connectivity Products

April 1, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 22, 2024, 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 encourage members to contribute liquidity to the Exchange by offering those that maintain a particular minimum trading volume lower fees for specified market data and connectivity products.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on September 1, 2024.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to reward firms that meet a minimum average daily displayed volume with lower fees for Non-Display Usage and the Exchange's 40Gb and 10Gb Ultra high-speed connection to the Exchange.[3]

Non-Display Usage

Non-Display Usage is any method of accessing Nasdaq U.S. information that involves access or use by a machine or automated device without access or use of a display by a natural person. Examples of Non-Display Usage include, but are not limited to:

- Automated trading;
- Automated order/quote generation and/or order/quote pegging;
- Price referencing for use in algorithmic trading;
- Price referencing for use in smart order routing;
- Program trading and high frequency trading;
- Order verification;
- Automated surveillance programs;
- Risk management;
- Automatic order cancellation, or automatic error discovery;
- Clearing and settlement activities;
- Account maintenance (*e.g.,* controlling margin for a customer account); and
- ''Hot'' disaster recovery.

Although either top-of-book or depth-of-book data can be used for Non-Display Usage, the proposal modifies fees for depth-of-book data only.[4]

Non-Display fees are currently assessed on a per-subscriber[5] or per-firm basis. Monthly fees are $375 per Subscriber for 1–39 subscribers; $15,000 per firm for 40–99 subscribers; $30,000 per firm for 100–249 subscribers; and $75,000 per firm for 250 or more subscribers.

Under the proposed rule change, a member firm that meets the minimum ADV threshold discussed below would continue to pay those fees.

Firms that do not meet the minimum ADV threshold, however, as well as non-member firms, would pay the new monthly fees of $500 per subscriber for 1–39 subscribers; $20,000 per firm for 40–99 subscribers; $40,000 per firm for 100–249 subscribers; and $100,000 per firm for 250 or more subscribers.

Fiber Connections to the Exchange (40Gb and 10Gb Ultra)

Nasdaq offers customers the opportunity to co-locate their servers and equipment within the Nasdaq Data Center,[6] allowing participants an opportunity to reduce latency and network complexity. Nasdaq offers a variety of connectivity options to fit a firm's specific networking needs, including the high-speed 40Gb and 10Gb Ultra networks.

All of Nasdaq's colocation and connectivity options offer customers access to any or all Nasdaq exchanges through a single connection.[7] For example, a firm that is a member of all six Nasdaq exchanges that purchases services in the Nasdaq Data Center such as a 40G fiber connection, cabinet space, cooling fans, and patch cables only purchases these products or services once to use them for all six Nasdaq exchanges.

Nasdaq currently charges members an ongoing monthly fee of $21,100 for the 40Gb fiber connection and $15,825 for the 10Gb Ultra connection to the Nasdaq exchanges. Under the proposed rule change, a firm that meets the minimum ADV threshold would continue to pay those fees.

Member firms that do not meet the minimum ADV threshold discussed below, as well as non-member firms, would pay the new monthly fee of $23,700 for the 40Gb fiber connection and $17,800 for the 10Gb Ultra connection.

Minimum ADV

The proposal introduces the new term ''Minimum ADV,'' which will mean the introduction by a member of at least one million shares of added executed displayed liquidity on average per trading day in all securities through one or more of the member's market participant identifiers (''MPIDs'') on the Nasdaq Market Center. Average daily volume is calculated as the total volume of shares executed for all added

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] This proposal was initially filed on March 6, 2024, as SR–Nasdaq–2024–011. On March 20, 2024, that filing was withdrawn and replaced with SR–Nasdaq–2024–015. On March 22, 2024, SR–Nasdaq–2024–015 was withdrawn and replaced with the instant filing due to a technical error.

[4] *See* Equity 7, Section 123 (Nasdaq Depth-of-Book data).

[5] ''Subscriber'' is defined as a device or computer terminal or an automated service which is entitled to receive information.

[6] *See* Nasdaq Co-Location (CoLo) Services, available at *https://www.nasdaqtrader.com/trader.aspx?id=colo;* Stock Exchange Data Center & Trading, available at *https://www.nasdaq.com/solutions/nasdaq-co-location.*

[7] *See* Securities Exchange Act Release No. 84571 (November 9, 2018), 83 FR 57758 (November 16, 2018) (SR–Nasdaq–2018–086).

displayed orders in all securities during the trading month divided by the number of trading days in that month, averaged over the six-month period preceding the billing month, or the date the firm became a member, whichever is shorter. New members will be deemed to meet the Minimum ADV for the first month of operation. Minimum ADV excludes sponsored access by a member on behalf of a third party. The minimum ADV threshold was designed to be accessible to all members to promote wide engagement with the Exchange.

Nasdaq does not expect any member to be disadvantaged by the proposal. Nasdaq is a maker-taker platform and, as such, offers rebates to members that offer displayed liquidity. With these rebates, no member should have any difficulty posting and executing sufficient displayed liquidity to meet the ADV threshold. The threshold is, moreover, set at a level that Nasdaq believes any member—even smaller members—should be able to meet without significant effort. Because the threshold applies to displayed liquidity only, the proposal should not impact the Best Execution obligations of any member. If all members were to meet this threshold, the proposal would add an incremental 60–80 million shares to Nasdaq's accessible liquidity.

Non-members that, by definition, do not post displayed liquidity to the market would pay the higher fees. This is because the non-members do not directly contribute order flow to the Exchange, but nevertheless benefit from that order flow through tighter spreads, better prices, and the other advantages of a more liquid platform, as discussed in further detail under Statutory Basis.

The Proposal Will Promote Competition Among Trading Venues

Exchanges, like all trading venues, compete as platforms. All elements of the platform—trade executions, market data, connectivity, membership, and listings—operate in concert. Trade executions increase the value of market data; market data functions as an advertisement for on-exchange trading; listings increase the value of trade executions and market data; and greater liquidity on the exchange enhances the value of ports and colocation services.

As discussed under Statutory Basis, we have attached a data-based analysis demonstrating how platform competition works entitled ''How Exchanges Compete: An Economic Analysis of Platform Competition'' as Exhibit 3. The paper explains that exchanges are multi-sided platforms, whose value is dependent on attracting users to multiple sides of the platform. Issuers need investors, and every trade requires two sides to trade. To make its platform attractive to multiple constituencies, an exchange must consider inter-side externalities, meaning demand for one set of platform services depends on the demand for other services. This proposal is designed to promote competition by providing an incentive for members to provide liquidity (therefore attracting investors and increasing the overall value of the platform) through charging lower fees for other platform services (*i.e.,* market data and connectivity). This will lead to more displayed liquidity on the Exchange, enhancing and enriching the market data distributed to the industry, which then increases the amount of interest in the platform. This will also enable the Exchange to offer investors a more robust, lower cost-trading experience through tighter spreads and more efficient trading as discussed in Exhibit 3, placing it in a better competitive position relative to other exchanges and trading venues.[8]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[10] 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.

Fees Produced in a Competitive Environment Are an Equitable Allocation of Reasonable Dues, Fees, and Other Charges

Reliance on competitive solutions is fundamental to the Act. Where significant competitive forces constrain fees, fee levels meet the Act's standard for the ''equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using its facilities,'' [11] unless there is a substantial countervailing basis to find that a fee does not meet some other requirement of the Act.[12] Evidence of platform competition demonstrates that each exchange product is sold in a competitive environment, and its fees will be an equitable allocation of reasonable dues, fees, and other charges, provided that nothing about the product or its fee structure impairs competition.[13]

Congress directed the Commission to ''rely on 'competition, whenever possible, in meeting its regulatory responsibilities for overseeing the SROs and the national market system.' '' [14] Following this mandate, the Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention to determine prices, products, and services in the securities markets.

In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and recognized that regulation of the national market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [15]

As a result, the Commission has long relied on competitive forces to determine whether a fee proposal is equitable, fair, reasonable, and not unreasonably or unfairly discriminatory. In 2008, the Commission explained that ''[i]f competitive forces are operative, the self-interest of the exchanges themselves will work powerfully to constrain unreasonable or unfair behavior.'' [16] In 2019, Commission Staff reaffirmed that ''[i]f significant competitive forces constrain the fee at issue, fee levels will be presumed to be fair and reasonable . . . .'' [17]

Accordingly, ''the existence of significant competition provides a substantial basis for finding that the terms of an exchange's fee proposal are equitable, fair, reasonable, and not

[8] To the degree that the additional liquidity is moved from off-exchange venues to on-exchange platforms, overall market transparency will improve as well.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4) and (5).

[11] *See* 15 U.S.C. 78f(b)(4).

[12] *See* U.S. Securities and Exchange Commission, ''Staff Guidance on SRO Rule filings Relating to Fees'' (May 21, 2019), available at *https://www.sec.gov/tm/staff-guidance-sro-rule-filings-fees* (''Fee Guidance'') (''If significant competitive forces constrain the fee at issue, fee levels will be presumed to be fair and reasonable, and the inquiry is whether there is a substantial countervailing basis to find that the fee terms nevertheless fail to meet an applicable requirement of the Exchange Act (*e.g.,* that fees are equitably allocated, not unfairly discriminatory, and not an undue burden on competition).'').

[13] Nothing in the Act requires proof of product-by-product competition.

[14] *NetCoalition* v. *SEC,* 715 F.3d 342, 534–35 (D.C. Cir. 2013); *see also* H.R. Rep. No. 94–229 at 92 (1975) (''[I]t is the intent of the conferees that the national market system evolve through the interplay of competitive forces as unnecessary regulatory restrictions are removed.'').

[15] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[16] *See* Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770 (December 9, 2008) (SR–NYSEArca–2006–21).

[17] *See* Fee Guidance, *supra* n.10.

unreasonably or unfairly discriminatory.'' [18] Consistent with the Commission's longstanding focus on competition, Commission Staff have indicated that they would only look at factors outside of the competitive market if a ''proposal lacks persuasive evidence that the proposed fee is constrained by significant competitive forces.'' [19]

Nothing in the Act Requires an Examination of Fees in Isolation

The Act mandates the ''equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using its facilities.'' [20] This provision refers generally to ''reasonable dues, fees, and other charges'' as a whole, not individual fees. Nothing in the Act requires the individual examination of specific product fees in isolation. Provided that a proposed rule change does not in and of itself undermine competition, evidence of platform competition is sufficient to show that the product operates in a competitive environment.

A determination of whether a proposal permits unfair discrimination between customers, issuers, brokers, or dealers remains a separate product-specific inquiry.

The Commission Has Recognized That Exchanges Are Subject to Significant Competitive Forces in the Market for Order Flow

The fact that the market for order flow is competitive has long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated, ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers.' '' [21]

All Exchange Products Are Subject to Competition—Not Just Those Directly Related to Order Flow

As discussed more fully in our analysis, ''How Exchanges Compete: An Economic Analysis of Platform Competition'' (Exhibit 3), competition is not limited to order flow. Data shows that the combination of explicit all-in costs to trade and other implicit costs has largely equalized the cost to trade across venues.[22] This is a function of the fact that, if the all-in cost to the user of interacting with an exchange exceeds market price, customers can and do shift their purchases and trading activity to other exchanges, and therefore the exchange must adjust one or more of its fees to attract customers.

This conclusion is particularly striking given that different exchanges engage in a variety of business models and offer an array of pricing options to appeal to different customer types. The largest exchanges operate maker-taker platforms, offering rebates to attract trading liquidity, which allows them to maintain actionable quotes with high liquidity and offer high-quality market data. The negative price charged to liquidity providers through rebates is part of the platform because it serves to create features attractive to other participants, including oftentimes tight spreads, actionable and lit quotes, and more valuable market data.

Inverted venues, in contrast, have the opposite price structure—liquidity providers pay to add liquidity, while liquidity takers earn a rebate. These platforms offer less liquidity, but better queue priority, faster fills, and lower effective spreads for investors. There are a wide range of other pricing models and product offerings among the dozens of lit and unlit trading venues that compete in the marketplace in addition to these examples.

The different strategies among exchanges also manifest in the pricing of other services, such as market data and connectivity. Some exchanges charge for such services, while others charge little or nothing (typically because the exchange is new or has little liquidity), just as some exchanges charge a fee per trade, while others pay rebates.

In assessing competition for exchange services, we must consider not only explicit costs, such as fees for trading, market data, and connectivity, but also the *implicit* costs of trading on an exchange. The realized spread, or markout, captures the implicit cost to trade on a platform.

The concept of markout was created by market makers trying to capture the spread while providing a two-sided (bid and offer) market. For market makers, being filled on the bid or the offer can cause a loss if the fill changes market prices. For example, a fill on a market maker's bid just as the stock price falls results in a ''virtual loss,'' because the market maker has a long position with a new bid lower than the fill.

Negative markouts can be beneficial. For example, if an institutional investor is working a large buy order, negative markouts represent fills as the market

[18] *See id.*

[19] *See id.* In the Fee Guidance, the Staff indicated that ''[w]hen reviewing rule filing proposals . . . [it] is mindful of recent opinions by the D.C. Circuit,'' including *Susquehanna International Group, LLP* v. *SEC,* 866 F.3d 442 (D.C. Cir. 2017). However, the D.C. Circuit's decision in *Susquehanna* is irrelevant to the Commission's review of immediately effective SRO fee filings. *Susquehanna* involved the Commission's approval of a rule proposed under Section 19(b)(2) of the Act, not its evaluation of whether to temporarily suspend an SRO's immediately effective fee filing under Section 19(b)(3). A comparison of Sections 19(b)(2) and 19(b)(3) of the Act makes clear that the Commission is not required to undertake the same independent review, and make the same findings and determinations, for Section 19(b)(3) filings that it must for Section 19(b)(2) filings. In particular, Section 19(b)(2) requires the Commission to ''find[ ] that [a] proposed rule change is consistent with the'' Act before approving the rule. 15 U.S.C. 78s(b)(2)(C)(i). Section 19(b)(3), by contrast, imbues the Commission with discretion, stating that it ''may temporarily suspend'' an immediately effective rule filing where ''it appears to the Commission that such action is necessary or appropriate.'' As the Supreme Court has explained, statutes stating that an agency ''may''—but need not—take certain action are ''written in the language of permission and discretion.'' *S. Ry. Co.* v. *Seaboard Allied Milling,* 442 U.S. 444, 455 (1979); *see also Crooker* v. *SEC,* 161 F.2d 944, 949 (1st Cir. 1947) (per curiam). The ''contrast'' between Sections 19(b)(2) and 19(b)(3), the Commission itself has explained, ''reflects the fundamental difference in the way Congress intended for different types of rules to be treated.'' Brief of Respondent SEC, *NetCoalition* v. *SEC,* 715 F.3d 342 (D.C. Cir. 2013) (Nos. 10–1421 et al.); *see also id.* at 42–43 (''[W]hile the Commission's authority to suspend a fee under Subsection (3)(C) is permissive, its duties under Subsection (2) are stated in mandatory terms.''). Thus, neither *Susquehanna,* nor Section 19(b)(3) of the Act, requires the Commission to make independent findings that an immediately effective SRO fee filing such as this one is consistent with the Act. To the degree that the *Susquehanna* decision is applicable to any Commission action, however, the court held that the Commission is required to ''itself find or determine'' that a proposal meets statutory requirements, explaining that the Commission is ''obligated to make an independent review'' of an SRO's proposal, and not rely solely on the work of the SRO. *See* 866 F.3d at 446.

[20] *See* 15 U.S.C. 78f(b)(4).

[21] *See NetCoalition,* 615 F.3d at 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[22] Competition across platforms constrains platform fees and results in ''all-in'' costs becoming equal across platforms. The Staff Guidance on SRO Rule Filings Relating to Fees, however, states that platform competition requires that the ''overall *return* of the platform, rather than the *return* of any particular fees charged to a type of customer, . . . be used to assess the competitiveness of the platform's market,'' and that ''[a]n SRO that wishes to rely on total platform theory must provide evidence demonstrating that competitive forces are sufficient to constrain the SRO's aggregate return across the platform.'' See Fee Guidance, supra n.10 (emphasis added). We do not know, and cannot determine, whether returns (as opposed to fees) are equalized across platforms, because we do not have detailed cost information from other exchanges. An analysis of returns, however, is unnecessary to show that competition constrains fees given that, as we demonstrate below, platform competition can be demonstrated solely by examining costs to users.

falls, allowing later orders to be placed sooner, and likely at a better price, reducing the opportunity costs as well as explicit cost of building the position.

Data suggests that market participants employ sophisticated analytic tools to weigh the cost of immediate liquidity and lower opportunity costs against better spread capture (lower markouts) and explicit trading costs. As discussed in greater detail in Exhibit 3, the venues with the highest explicit costs—typically inverted and fee-fee venues—have the lowest implicit costs from markouts and vice versa. Higher positive markouts mean more spread capture, but those venues also tend to have the highest explicit costs, and provide the least liquidity, and positive externalities, to the market.

Considering both the explicit costs charged by exchanges for their various joint products and the implicit costs incurred by traders to trade on various exchanges, the data show that all-in trading costs across exchanges are largely equalized, regardless of different trading strategies offered by each platform for each individual service.

As such, platform competition has resulted in a competitive environment in the market for exchange services, in which trading platforms are constrained by other platforms' offerings, taking into consideration the all-in cost of interacting with the platform. This constraint is a natural consequence of competition and demonstrates that no exchange platform can charge excessive fees and expect to remain competitive, thereby constraining fees on all products sold as part of the platform. The existence of platform-level competition also explains why some consumers route orders to the exchange with the highest explicit trading costs even though other exchanges offer free or a net rebate for trading.[23]

Exchanges Compete at Both the Platform and Product Level

Exchange customers are differentiated in the value they place on the different products offered by exchanges and in their willingness to pay for those products. This occurs both on a firm-wide and a transaction basis; for example, individual customers ''multi-home'' on various platforms, and are thus able to route different trades to different platforms to take advantage of favorable economics offered on a trade-to-trade basis.

Exchanges compete by offering differentiated packages of pricing and products to attract different categories of customer. As in any competitive market, consumers will ''vote with their feet,'' incentivizing platforms to supply an array of pricing and product offerings that suit diverse consumer needs far more effectively than a uniform, one-size-fits-some rigid product offering. If an exchange's pricing for a particular product gets out of line, such that its total return is boosted above competitive levels, market forces will discipline that approach because competing exchanges will quickly attract customer volume through more attractive all-in trading costs.

In addition, if a particular package of pricing and products is not attractive to a sufficient volume of customers in a particular category, those customers may elect not to purchase the service. This is why exchanges compete at a product level, as well as based on all-in trading costs.

Exchanges Compete With Off-Exchange Trading Platforms in Addition to Other Exchanges

As the SEC recently noted in its market infrastructure proposal,[24] the number of transactions completed on non-exchange venues has been growing. Allowing exchanges to compete as platforms will help exchanges compete against non-exchange venues, and, to the degree order flow is shifted from non-exchange to exchange venues, overall market transparency will improve.[25]

Exchanges have a unique role to play in market transparency because they publish an array of pre- and post-trade data that non-exchange venues, almost entirely, do not. Greater transparency benefits non-exchange venues by enabling them to provide more accurate pricing to their customers, and by helping such venues set their own prices, benchmark, analyze the total cost of ownership, and assess their own trading strategies.

Allowing exchanges to compete effectively as platforms has other positive network effects. Larger trading platforms offer lower average trading costs. As trading platforms attract more liquidity, bid-ask spreads tighten, search costs fall (by limiting the number of venues that a customer needs to check to assess the market), and connection costs decrease, as customers have no need to connect to all venues.[26] The whole is therefore greater (in the sense that it is more efficient) than the sum of the parts.

This is not to say that smaller established trading platforms do not have a role to play. They provide specialized services that cater to individual customer needs. These specialized services help the smaller exchanges grow by driving liquidity to their platforms, and, if they are successful, achieve the economies of scale that benefit the larger enterprises. Because the total costs of interacting with an exchange are roughly equal, smaller exchanges offset higher trading costs with lower connectivity, market data, or other fees. While the mix of fees will change as exchanges grow, the all-in cost of interacting with the exchange remains roughly the same.

Acknowledging that exchanges compete as platforms and approving fees expeditiously on that basis will improve the ability of exchanges to compete against non-exchange venues, and, to the degree order flow is shifted to exchanges, both transparency and efficiency will improve.

The Proposed Fees Are Equitable and Reasonable Because They Will Be Subject to Competition

This proposal offers member firms an incentive to display liquidity through lower non-display and connectivity fees. The intent is to generate a ''virtuous cycle,'' in which the proposed fee structure will attract more liquidity to the Exchange, making it a more attractive trading venue, and thereby attracting more liquidity.

Incentive programs have been widely adopted by exchanges, and are reasonable, equitable, and non-discriminatory because they are open on an equal basis to similarly situated members and provide additional benefits or discounts that are reasonably related to the value to an exchange's market quality and activity.[27]

[23] Empirical evidence also shows that market data is more valuable from exchanges with more liquidity. Many customers decide not to take data from smaller markets, even though they are free or much lower cost than larger markets.

[24] *See* Regulation NMS: Minimum Pricing Increments, Access Fees, and Transparency of Better Price Orders, Securities Exchange Act Release No. 96494 (File No. S7–30–22), available at *https://www.sec.gov/rules/proposed/2022/34-96494.pdf.*

[25] Non-exchange venues rely on market data distributed by exchanges to set prices. Greater transparency allows both exchange and non-exchange venues to operate more effectively and efficiently.

[26] In addition, Nasdaq's experience shows that fewer customers connect with smaller trading venues than with larger venues.

[27] *See, e.g.,* Securities Exchange Act Release No. 92493 (July 26, 2021), 86 FR 41129 (July 30, 2021) (SR–CboeEDGX–2021–034) (proposal to provide discount to new members that meet certain volume thresholds, noting that ''relative volume-based incentives and discounts have been widely adopted by exchanges . . . and are reasonable, equitable and non-discriminatory because they are open on an equal basis to similarly situated members and provide additional benefits or discounts that are

Continued

The proposal will contribute to market quality because it will help bring new order flow to the Exchange. Greater displayed liquidity on the Exchange offers investors deeper, more liquid markets and execution opportunities.

Increased order flow benefits investors by deepening the Exchange's liquidity pool, potentially providing greater execution incentives and opportunities, offering additional flexibility for all investors to enjoy cost savings, supporting the quality of price discovery, promoting market transparency, and lowering spreads between bids and offers and thereby lowering investor costs. To the degree that liquidity is attracted from dark venues, that liquidity also increases transparency for the market overall, providing investors with more information about market trends.

The proposal will help members that meet the minimum ADV threshold maintain lower costs and will benefit them through the many positive externalities associated with a more liquid exchange.

The competition among exchanges as trading platforms, as well as the competition between exchanges and alternative trading venues, constrain exchanges from charging excessive fees for any exchange products, including trading, listings, ports, and market data. Indeed, the fees that arise from the competition among trading platforms may be too low because they fail to reflect the benefits to the market as a whole of exchange products and services, allowing other venues to free-ride on these investments by the exchange platforms, increasing fragmentation and search costs.

As long as total returns are constrained by competitive forces—as demonstrated in detail by the report provided as Exhibit 3—there is no regulatory basis to be concerned with pricing of particular elements offered on a platform. Indeed, regulatory constraints in this environment are likely to *reduce* consumer welfare by constraining certain exchanges from offering packages of pricing and products that would be attractive to certain sets of consumers, thus impeding competition with venues that are not subject to the same regulatory limitations and reducing the benefits of competition to customers.

The Proposal Is Not Unfairly Discriminatory

The proposal is not unfairly discriminatory. Non-Display Usage and the Exchange's 40Gb and 10Gb Ultra high-speed connections will be offered to all members and non-members on like terms. It is also not unfair to charge more to firms that do not directly contribute order flow to the Exchange, but nevertheless benefit from that order flow through tighter spreads, better prices, and the other advantages of a more liquid platform.

Specifically, the proposal is not unfairly discriminatory with respect to either members or non-members.

With respect to members, all members that meet the ADV threshold will be charged lower fees. With respect to smaller members, Nasdaq offers rebates to members that offer displayed liquidity. With these rebates, any member—even smaller members—should have the ability to post sufficient displayed liquidity to meet the ADV threshold.

The proposal is not unfairly discriminatory with respect to non-members broker-dealers, which include brokers routing trades through members and off-exchange trading platforms that use exchange data to execute trades, because they have the option of becoming members to obtain lower fees under the proposal, and because they realize the benefits of higher liquidity—including tighter spreads and better prices—and it is not unfair discrimination to charge a higher fee for that benefit.

The proposal is not unfairly discriminatory with respect to non-member firms that are not broker-dealers, such as market data vendors and index providers, because they also benefit from the value that the additional liquidity generated by this proposal will provide to the trading platform. As noted above, incentivizing higher levels of liquidity enhances and enriches the market data distributed to the industry, and increases the overall value of platform. It is not unfair for such parties to pay a higher fee to reflect the greater value of the platform.

Discounts for specific categories of market participants are well-established; examples include non-professional fees, broker-dealer enterprise licenses, and a media enterprise license.[28]

For all of the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[29] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Rather, as discussed above, the Exchange believes that the proposed changes would increase competition by attracting additional liquidity to the Exchange, which the Exchange believes will enhance market quality, thereby promoting market depth, price discovery, and transparency and enhancing order execution opportunities for member organizations. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [30]

Intra-market Competition. Nothing in the proposal burdens intra-market competition (the competition among consumers of exchange data) because the proposed fee structure would be available to all similarly situated market participants, and, as such, the proposed change would not impose a disparate burden on different market participants.

Intermarket Competition. Nothing in the proposal burdens intermarket competition (the competition among self-regulatory organizations) because competitors are free to modify their own fees in response.

As previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and direct their order flow to, including other equities exchanges, off-exchange venues, and alternative trading systems. Participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those

reasonably related to (i) the value to an exchange's market quality and (ii) associated higher levels of market activity . . . .'') (not suspended by Commission); *see also* Securities Exchange Act Release No. 53790 (May 11, 2006), 71 FR 28738 (May 17, 2006) (SR–Phlx–2006–04) (''The Commission recognizes that volume-based discounts of fees are not uncommon, and where the discount can be applied objectively, it is consistent with Rule 603. For the same reasons noted above, the Commission believes that the fee structure meets the standard in section 6(b)(4) of the Act in that the proposed rule change provides for the equitable allocation of reasonable dues, fees, and other charges among the Exchange's members and issuers and other persons using its facilities.'').

[28] *See, e.g.,* The Nasdaq Stock Market, Price List—U.S. Equities, available at *http://www.nasdaqtrader.com/Trader.aspx?id=DPUSData* (providing discounts for Non-Professional subscribers for Nasdaq TotalView and other market data products, enterprise licenses for broker-dealers for multiple market data products, and a digital media enterprise license for Nasdaq Basic).

[29] 15 U.S.C. 78f(b)(8).

[30] Securities Exchange Act Release No. 51808, 70 FR 37496, 37498–99 (June 29, 2005) (Regulation NMS).

other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges and with off-exchange venues.

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.[31]

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–2024–016 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–2024–016. 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 submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also 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–2024–016 and should be submitted on or before April 26, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[32]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–07227 Filed 4–4–24; 8:45 am]

BILLING CODE 8011–01–P

[31] 15 U.S.C. 78s(b)(3)(A)(ii).

[32] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99881; File No. SR–NYSEARCA–2024–30]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.4–E

April 1, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 25, 2024, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.4–E (Ex-Dividend or Ex-Right Dates) to conform to amendments to Rule 15c6–1(a) of the Act to shorten the standard settlement cycle for most broker-dealer transactions from two business days after the trade date (''T+2'') to one business day after the trade date (''T+1''). The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

On March 6, 2023, the Commission adopted amendments to Rule 15c6–1(a) of the Act to shorten the standard settlement cycle for most broker-dealer transactions from T+2 to T+1.[3] Accordingly, the Exchange proposes to amend Rule 7.4–E to conform with the amendments to Rule 15c6–1(a) and reflect a standard settlement cycle of T+1.

Rule 7.4–E currently provides that transactions in stocks traded ''regular way'' are generally ''ex-dividend'' or ''ex-rights'' on the business day preceding the record date fixed by the company or the date of the closing of transfer books. The rule further provides that, if the record date or closing of transfer books occur on a day other than a business day, transactions would be ''ex-dividend'' or ''ex-rights'' on the second preceding business day.

The Exchange proposes to amend Rule 7.4–E to provide, in conformity

[3] *See* Securities Exchange Act Release No. 96930, 88 FR 13872 (March 6, 2023) (''T+1 Adopting Release'').

with the transition to a T+1 settlement cycle, that transactions in stocks traded ''regular way'' generally will be ''ex-dividend'' or ''ex-rights'' on the record date fixed by the company or the date of the closing of transfer books, or if the record date or closing of transfer books occur on a day other than a business day, on the preceding business day.

Implementation

The Exchange proposes that the operative date of this proposed rule change will be Tuesday, May 28, 2024, which is the compliance date specified in the T+1 Adopting Release, or such later date as may be announced by the Commission for compliance with the amendments to Rule 15c6–1(a) set forth in the T+1 Adopting Release.[4] With the implementation of the T+1 settlement cycle and as described in the proposed changes outlined above, the ex-dividend date for ''normal'' distributions will be the same business day as the record date. Accordingly, the Exchange proposes that Wednesday, May 29, 2024 would be the first date to which the proposed rules described herein would apply (*i.e.,* the first record date to which the new ex-dividend date rationale will be applied). During the implementation of the T+1 settlement cycle, the Exchange proposes that the ex-dividend dates will be as follows:

Record date	Ex-dividend date
May 24, 2024	May 23, 2024.
May 28, 2024	May 24, 2024.
May 29, 2024	May 29, 2024.

A record date of Friday, May 24, 2024 would be a date prior to the effective date of the amendments to Rule 15c6–1(a) of the Act to shorten the standard settlement cycle for most broker-dealer transactions from T+2 to T+1.[5] The rules described above would apply to this record date in their current form and, thus, the ''ex-dividend date'' would be the first business day preceding the record date or Thursday, May 23, 2024. Monday, May 27, 2024 is Memorial Day, which is an Exchange holiday; accordingly, there would be no record date on a holiday. A record date of Tuesday, May 28, 2024 would also fall under the Exchange's current rules, and the first business day preceding such record date would be Friday, May 24, 2024. On Wednesday, May 29, 2024, the proposed rules described above would apply, such that, for the record date of May 29, 2024, the ''ex-dividend date'' would be the same business day.

The Exchange will issue a Trader Notice regarding the implementation of the proposed rule change and T+1 settlement cycle, which date would correspond with the industry-led transition to a T+1 standard settlement, and the compliance date of the Commission's amendment of Rule 15c6–1(a) of the Act to require standard settlement no later than T+1.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[6] in general, and furthers the objectives of Section 6(b)(5) of the Act,[7] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, 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 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.

In particular, the proposed rule change would amend the Exchange's rules to reflect a standard settlement cycle of T+1, in support of the industry-led initiative to shorten the settlement cycle to one business day. Moreover, the proposed rule change is consistent with the Commission's amendments to Rule 15c6–1(a) of the Act to require standard settlement no later than T+1. The Exchange believes that the proposed rule change would provide regulatory certainty to facilitate the industry-led move to a T+1 settlement cycle. The Exchange further believes that, by shortening the time period for settlement of most securities transactions, the proposed rule change would protect investors and the public interest by reducing the number of unsettled trades in the clearance and settlement system at any given time, thereby reducing the risk inherent in settling securities transactions to clearing corporations, their members, and public investors.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue, but rather to support the industry's transition to a T+1 regular-way settlement cycle in conformity with the Commission's amendment of Rule 15c6–1(a). The proposed change amends the Exchange's rules pertaining to securities settlement, which rules would apply uniformly to all contracts for the purchase or sale of a security (other than exempted securities) that provide for payment of funds and delivery of securities that occur on the Exchange or other self-regulatory organizations, and is intended to facilitate the industry-wide transition to a T+1 settlement cycle. The Exchange also believes that the proposed rule change will serve to promote clarity and consistency in its rules, thereby reducing burdens on the marketplace and facilitating investor protection. Accordingly, the Exchange believes that the proposed changes do not impose any burden on competition other than that necessary to implement the amendments to Rule 15c6–1(a) of the Act as set forth in the T+1 Adopting Release.[8]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) significantly affect the protection of investors or the public interest;

(ii) impose any significant burden on competition; and

(iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act.

[4] *See id.*

[5] *See* note 3, *supra.*

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] *See* note 3, *supra.*

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–NYSEARCA–2024–30 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSEARCA–2024–30. 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 submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also 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–NYSEARCA–2024–30 and should be submitted on or before April 26, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–07216 Filed 4–4–24; 8:45 am]

BILLING CODE 8011–01–P

[9] 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 May 6, 2024.

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 Curtis Rich, Agency Clearance Officer at *curtis.rich@sba.gov;* (202) 205–7030 or from *www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: SBA Form 172 is only used by lenders for loans that have been purchased by SBA and are being serviced by approved SBA lending partners. The lenders use the SBA Form 172 to report loan payment data to SBA on a monthly basis. The purpose of this reporting is to (1) show the remittance due SBA on a loan serviced by participating lending institutions (2) update the loan receivable balances.

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 3245–0131.

Title: Transaction Report on Loans Serviced by Lender.

Description of Respondents: SBA Lenders.

SBA Form Number: SBA Form 172.

Estimated Number of Respondents: 542.

Estimated Annual Responses: 28,256.

Estimated Annual Hour Burden: 4,709.

Curtis Rich,

Agency Clearance Officer.

[FR Doc. 2024–07229 Filed 4–4–24; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF STATE

[Public Notice: 12365]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''Thomas Schütte'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary display in the exhibition ''Thomas Schütte'' at The Museum of Modern Art, New York, New York, and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of

Authority No. 523 of December 22, 2021.

Nicole L. Elkon,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2024–07251 Filed 4–4–24; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 12364]

60-Day Notice of Proposed Information Collection: Border Crossing Survey—U.S. Embassy Jerusalem Reporting Form

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to June 4, 2024.

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

- *Web:* Persons with access to the internet may comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering ''Docket Number: DOS–2024–0010'' in the Search field. Then click the ''Comment Now'' button and complete the comment form.
- *Email: OCS-Logistics@state.gov.*
- *Regular Mail:* Send written comments to U.S. Department of State, CA/OCS, SA–17, 10th Floor, Washington, DC 20522–1710.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Thales Dus at *CA-OCS-Logistics@state.gov* or 202–485–6020.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* U.S. Embassy Jerusalem Incident Reporting Form.
- *OMB Control Number:* 1405–0260.
- *Type of Request:* Extension of a Currently Approved Collection.
- *Originating Office:* CA/OCS.
- *Form Number:* None.
- *Respondents:* U.S. Citizens.
- *Estimated Number of Respondents:* 3293.
- *Estimated Number of Responses:* 3,293.
- *Average Time per Response:* 20 minutes per response.
- *Total Estimated Burden Time:* 1,098 hours.
- *Frequency:* On occasion.
- *Obligation to Respond:* Voluntary.

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

The Government of Israel (GOI) and the United States signed a Memorandum of Understanding (MOU) on Extension of Reciprocal Privileges and the Visa Waiver Program (VWP) in July 2023. This collection is used to monitor the GOI's commitment to provide non-discriminatory treatment of all U.S. citizens travelling through Israeli controlled ports of entry and checkpoints in Israel, the West Bank, and Gaza and to be able to fully assess whether Israel is meeting the VWP reciprocity requirement as laid out in the MOU. This online survey is to allow U.S. citizens to easily and voluntarily report their experiences seeking entry into Israel, including instances of discrimination, to the U.S. Embassy in Jerusalem. U.S. citizens complete the form electronically, allowing for immediate and automatic data collection of form responses.

Methodology

This information will be collected via Microsoft survey.

Angela M. Kerwin,

Deputy Assistant Secretary, Bureau of Consular Affairs/Office of Overseas Citizen Services, Department of State.

[FR Doc. 2024–07232 Filed 4–4–24; 8:45 am]

BILLING CODE 4710–06–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36525]

Savage Companies—Continuance in Control Exemption—Savage, Bingham & Garfield Railroad Company and Savage Tooele Railroad Company

Savage Companies (Savage) has filed a verified notice of exemption pursuant to 49 CFR 1180.2(d)(2) to continue in control of two non-connecting rail carriers—Savage, Bingham & Garfield Railroad Company (SBG), a Class III rail carrier, and Savage Tooele Railroad Company (STR), a noncarrier—upon STR becoming a Class III rail carrier.[1]

This transaction is related to two later-filed petitions for exemption. In the first, *Savage Tooele Railroad—Construction & Operation Exemption—Line of Railroad in Tooele County, Utah,* Docket No. FD 36616, STR is seeking Board authority to construct and operate approximately 11 miles of rail line in Tooele County, Utah. In the second, Union Pacific Railroad Company sought and received Board authority in *Union Pacific Railroad—Operation Exemption—in Tooele County, Utah,* FD 36741 (STB served Feb. 13, 2024), to reinstitute common carrier service over approximately 1.04 miles of line in Tooele County, Utah.[2]

Savage states that it will continue in control of SBG and STR upon STR becoming a Class III rail carrier. According to the verified notice, Savage owns and controls SBG and STR through a series of subsidiary holding companies, with Savage as the ultimate parent company. Savage has 81%

[1] By decision served September 30, 2021, the Board ordered this docket held in abeyance pending supplementation of the record and further Board action. Savage supplemented the record on October 19, 2021. Issuance of today's notice terminates the abeyance.

[2] This transaction is also related to a since-withdrawn verified notice of exemption in *Savage Tooele Railroad—Acquisition & Operation Exemption in Tooele County, Utah—Union Pacific Railroad,* Docket No. FD 36524. On May 26, 2022, the Board granted STR's motion to withdraw that notice, as STR discovered that the line it sought to acquire had been abandoned in 1983. STR subsequently sought authority to construct and operate a new line in Docket No. FD 36616.

control of a first-tier subsidiary named Savage Enterprises Holdings, LLC, which in turns owns 100% of a second-tier subsidiary named Savage Enterprises Intermediate, LLC, which in turn owns 100% of a third-tier subsidiary named Savage Enterprises, LLC. SBG and STR are wholly owned subsidiaries of Savage Enterprises, LLC, and are thus fourth-tier subsidiaries of Savage.

The exemption will become effective on May 1, 2024.

Savage represents that: (1) the lines of STR and SBG will not connect with one another; (2) the continuance in control transaction is not part of a series of anticipated transactions that would result in such a connection; and (3) the proposed transaction does not involve a Class I carrier. Therefore, the transaction is exempt from the prior approval requirements of 49 U.S.C. 11323. *See* 49 CFR 1180.2(d)(2).

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Section 11326(c), however, does not provide for labor protection for transactions under sections 11324 and 11325 that involve only Class III rail carriers. Accordingly, the Board may not impose labor protective conditions here because all of the carriers involved are Class III carriers.

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 April 24, 2024 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36525, 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, one copy of each pleading must be served on Thomas W. Wilcox, Law Office of Thomas W. Wilcox, LLC, 1629 K Street NW, Suite 300, Washington, DC 20006.

According to Savage, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: April 2, 2024.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Brendetta Jones,

Clearance Clerk.

[FR Doc. 2024–07294 Filed 4–4–24; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36616]

Savage Tooele Railroad Company—Construction and Operation Exemption—Line of Railroad in Tooele County, Utah

On June 30, 2022, Savage Tooele Railroad Company (STR),[1] a noncarrier, filed a petition for exemption under 49 U.S.C. 10502 from the prior approval requirements of 49 U.S.C. 10901 to construct and operate approximately 11 miles of rail line in Tooele County, Utah (the Line), connecting the Union Pacific Railroad Company (UP) Shafter Subdivision mainline at approximately milepost 897.94 near Burmester, Utah, to the new Lakeview Business Park in Grantsville, Utah (the Park). STR explains that the Line would reestablish the former Warner Branch connection to UP's Shafter Subdivision at Burmester, Utah, and that STR would provide common carrier service over the Line to enable tenants of the industrial park to ship and receive commodities and other products by rail. STR asked the Board to issue a preliminary decision addressing the transportation merits of the Line while the environmental review process was underway.

In a decision served on August 24, 2022, the Board instituted a proceeding under 49 U.S.C. 10502(b) and sought clarification on the plans for the right-of-way and track located between milepost 0.0 and milepost 1.04. *Savage Tooele R.R.—Const. & Operation Exemption—Line of R.R. in Tooele Cnty., Utah,* FD 36616, slip op. at 2 (STB served Aug. 24, 2022). Later, in a decision served on March 30, 2023, the Board denied STR's request for the Board to preliminarily address the transportation merits of the proposed Line prior to the completion of the environmental review process. *See Savage Tooele R.R.,* FD 36616 (STB served Mar. 30, 2023) (with Board Members Fuchs and Schultz dissenting). The Board concluded that STR had not shown any ''unique or compelling circumstances'' to justify a conditional grant. *Id.* at 2–3. No comments opposing the transportation merits of STR's petition were filed.

The Board's Office of Environmental Analysis (OEA) issued a Draft Environmental Assessment (Draft EA) on September 29, 2023, analyzing the potential environmental impacts of the Line and requesting public comments, as required by the National Environmental Policy Act (NEPA), 42 U.S.C. 4321–4370m–11. A Final Environmental Assessment (Final EA) containing additional environmental analysis and responding to the comments received on the Draft EA was issued on March 1, 2024. The Final EA recommends environmental conditions, including voluntary mitigation measures proposed by STR and mitigation developed by OEA, to avoid, minimize, or mitigate the potential environmental impacts of the proposed construction and operation of the Line.

After considering both the rail transportation merits and the potential environmental impacts, the Board will grant STR's petition for exemption, authorizing STR to construct and operate over the Line, subject to the environmental mitigation measures set forth in the Final EA (attached as Appendix A).

Background

According to STR, the Line would extend from the Park to an approximately 1.04-mile segment of track owned by UP connecting to UP's Shafter Subdivision at Burmester, Utah.[2] (Pet. 4–5; STR Supp. 1–2, Sept. 20, 2022.) The Line comprises a portion of the former Warner Branch, which was owned and operated by UP's predecessor, Western Pacific Railroad Company (WP). (Pet. 4.) WP sought and received authority to abandon the Warner Branch in 1983. (*Id.* (citing *W. Pac. R.R.—Aban. Exemption—in Tooele Cnty., Utah,* FD 30208 (ICC served Aug. 9, 1983); *see also id.* at 2 n.1 (representing that due diligence by UP and STR indicated that the railroad line ''had been formally abandoned by . . . 1983'').) STR then acquired UP's rights and interests in the right-of-way and track between milepost 1.04 and milepost 6.94. (*Id.*) STR notes that the right-of-way and track of the Warner Branch have remained largely intact; however, in 2004 and 2015, UP deeded two parcels of the right-of-way—approximately 0.54 miles—to adjacent landowners. (*Id.* at 5.) STR states that these parcels will need to be reacquired

[1] STR is a wholly owned subsidiary of Savage Enterprises, LLC, and both are subsidiaries of Savage Companies. (Pet. 3.)

[2] UP recently received an exemption from the Board to reinstitute common carrier service and operate over the 1.04-mile segment. *See Union Pac. R.R.—Operation Exemption—in Tooele Cnty., Utah,* FD 36741 (STB served Feb. 13, 2024).

and the track reconstructed, along with two at-grade rail crossings at State Highway 138 and Erda Way. (*Id.*) STR states that it plans to construct approximately five miles of new track extending the former Warner Branch into the Park, along with interchange and ancillary track within the Park, as well as approximately 2,500 feet of new interchange and ancillary track within the right-of-way near milepost 1.04. (*Id.* at 5–6.)

STR argues that construction and operation of the Line would provide common carrier freight service to and from the 1,700-acre Park through interchange with UP, thus providing tenant shippers with greater mode optionality, lower total emissions due to fewer truck movements, reduced overall truck traffic, improved road longevity, and greater business diversity within the Park itself. (*Id.* at 3–6; STR Supp. 1–2, Sept. 20, 2022.) The Board has received separate letters supporting STR's petition from the State of Utah and the Utah Department of Transportation, the World Trade Center Utah, Congressman John Curtis, and Congressman Chris Stewart. (*See* State of Utah Ltr., July 20, 2022; Utah Dep't of Transp. Ltr., July 15, 2022; World Trade Center Utah Ltr., July 15, 2022; Curtis Ltr., July 18, 2022; Stewart Ltr. July 27, 2022.) Following issuance of the Draft EA, the Board received a letter in support of the project, jointly signed by Utah Congressmen Burgess Owens, Blake D. Moore, and John Curtis. (*See* Owens, Moore, Curtis Ltr., Oct. 24, 2023.)

On February 27, 2024, STR's counsel filed a letter asking the Board issue a final decision on the merits of the petition no later than April 3, 2024. (*See* STR Ltr., Feb. 27, 2024.)

Discussion

Rail Transportation Policy Analysis. The construction and operation of new railroad lines requires prior Board authorization, either through a certificate under 49 U.S.C. 10901 or—as requested here—an exemption under 49 U.S.C. 10502 from the prior approval requirements of section 10901. Section 10901(c) directs the Board to grant rail construction proposals unless it finds the proposal ''inconsistent with the public convenience and necessity.'' *See Alaska R.R.—Constr. & Operation Exemption—A Rail Line Extension to Port MacKenzie, Alaska,* FD 35095, slip op. at 5 (STB served Nov. 21, 2011) (addressing the Board's construction exemption process), *aff'd sub nom. Alaska Survival* v. *STB,* 705 F.3d 1073 (9th Cir. 2013).

Under section 10502(a), the Board shall, to the maximum extent permissible, exempt a proposal to construct and operate a new rail line from the prior approval requirements of section 10901 when the Board finds that: (1) application of those procedures is not necessary to carry out the rail transportation policy (RTP) of 49 U.S.C. 10101; and (2) either (A) the proposal is of limited scope, or (B) the full application procedures are not necessary to protect shippers from an abuse of market power.

Based on the record, the proposed construction and operation—which was unopposed on the transportation merits—qualifies for an exemption under section 10502 from the formal application procedures of section 10901. The record shows that the Line, if constructed, would provide a rail transportation option to shippers and promote business diversity within the Park, as well as provide ''greater mode optionality for business park tenants, lower total emissions due to fewer truck movements, reduced overall truck traffic, and improved road longevity due to less wear and tear from trucks.'' (Pet. 3–4.) There is currently no rail service at the Park, forcing the shippers to use trucks for their transportation needs and limiting the Park's appeal to new businesses. (*Id.* at 3.) Moreover, no issues about the Line's current or future financial viability have been raised.

For all of these reasons, construction and operation of the Line clearly supports the RTP. By providing the Park's shippers with a freight rail option that does not currently exist, the Line would enhance the development and continuation of a sound rail transportation system with effective competition and coordination between rail carriers and other transportation modes, to meet the needs of the public. 49 U.S.C. 10101(4), (5). Introducing a new, competitive option to the truck-served park would also facilitate competition and the demand for service to establish reasonable rates for rail transportation. 49 U.S.C. 10101(1). Also, by supporting truck-to-rail diversions, the Line would increase overall energy efficiency, thereby encouraging and promoting energy conservations. 49 U.S.C. 10101(14). And as explained further below, because there would be no or de minimis environmental impacts with the final environmental mitigation recommended by OEA, exempting the proposed construction and operation would be consistent with 49 U.S.C. 10101(8). In addition, by exempting the proposed construction and operation from the requirements of section 10901, the Board would promote the RTP by minimizing the need for Federal regulatory control over the rail transportation system, reducing regulatory barriers to entry, and providing for the expeditious handling and resolution of regulatory proceedings. 49 U.S.C. 10101(1), (2), (15).

Consideration of the proposed construction and operation of the Line under section 10901 also is not necessary to protect shippers from an abuse of market power.[3] As explained, the Line would enhance competition by providing rail service where it does not currently exist, thereby creating an alternative mode of transportation for current and future shippers at the Park.

Environmental Analysis. NEPA requires Federal agencies to examine the environmental impacts of proposed Federal actions and to inform the public concerning those effects. *See Balt. Gas & Elec. Co.* v. *Nat. Res. Def. Council,* 462 U.S. 87, 97 (1983). Under NEPA and related environmental laws, the Board must consider significant potential beneficial and adverse environmental impacts in deciding whether to authorize the construction and operation of a new rail line as proposed, deny the proposal, or grant it with conditions (including environmental mitigation conditions). *Lone Star R.R.—Track Constr. & Operation Exemption—in Howard Cnty., Tex.,* FD 35874, slip op, at 4 (STB served Mar. 3, 2016). While NEPA prescribes the process that must be followed, it does not mandate a particular result. *See Robertson* v. *Methow Valley Citizens Council,* 490 U.S. 332, 350 (1989). Once the adverse environmental effects have been adequately identified and evaluated, the Board may conclude that other values outweigh the environmental costs. *Id.* at 350–51.

There has been a thorough environmental and historic review in this case. The Draft EA considered both STR's proposed action and the no-action alternative. The Draft EA explained that because the Line would be built on existing rail right-of-way, there would be fewer environmental impacts than would be the case with construction on an entirely new right-of-way. (Draft EA S–3.) The Draft EA concluded that STR's proposed action would have no or de minimis impacts in several environmental resource areas, including air quality, energy, land use, and historic resources. For resource areas that have the potential to be impacted,

[3] Given this finding regarding the lack of need for shipper protection, the Board need not determine whether the transaction is limited in scope. 49 U.S.C. 10502(a)(2).

including noise and grade crossing safety and delay, OEA proposed preliminary mitigation, including both voluntary mitigation and mitigation developed by OEA, to minimize those impacts. (*Id.* at S–5 to S–10.) The Draft EA also explained that an Environmental Impact Statement (EIS) is unnecessary and that an EA is the appropriate level of environmental documentation for this case. (*Id.* at 1–6.)

OEA received 21 comments on the Draft EA. (*See* Final EA App. I.) The Final EA, issued on March 1, 2024, responded to all comments received on the Draft EA. (*Id.* at S–6.) In response to comments arguing that environmental impacts from development of the Park should be treated as indirect impacts from construction of the Line, the Final EA explained that the Park already exists, is operating and serving shippers by truck, and that local jurisdictions have been supporting the Park and other industrial development projects in the area regardless of whether the Line is built. (*See, e.g.,* Final EA 3–74 to 3–76; *id.,* App. I at S–18.; *see also* Final EA 3–77 (explaining that impacts from development of an inland port located adjacent to the northern end of the Line would not be indirect impacts from the Line because, among other things, STR ''does not plan to serve the inland port development or any new or existing businesses outside the [Park]'').) In these circumstances, the Final EA considered reasonably foreseeable impacts from the Park and certain other projects located near the Line within its cumulative impacts analysis, and not as indirect impacts. (Final EA at 3–79.) The Final EA also recommended that any final decision by the Board authorizing the construction and operation of the Line be subject to the environmental mitigation conditions in the Final EA. (*Id.*)

The Board will adopt the analysis and conclusions made by OEA in both the Draft EA and Final EA, including OEA's final recommended environmental mitigation measures. (*See id.* at 4–1 to 4–12.) The Board is satisfied that OEA has taken the requisite hard look at the potential environmental impacts associated with the proposed construction and operation of the Line and properly determined that with the recommended environmental mitigation in the Final EA, the proposed Line will not have potentially significant environmental impacts, and that preparation of an EIS is unnecessary.

Conclusion

Construction and operation of the Line will give shippers a new freight rail option, which will support business diversification within the Park and more competitive transportation rates. With OEA's final recommended mitigation, there will be no potential for significant environmental impacts; indeed, the Line will facilitate the diversion of traffic from truck to rail, thereby increasing overall energy efficiency and reducing emissions from trucks. After carefully considering the transportation merits and environmental issues, the Board, considering the entire record, finds that the petition for exemption to allow STR's construction and operation of the approximately 11-mile line of railroad in Tooele County assessed in the Draft and Final EAs should be granted, subject to compliance with the environmental mitigation measures in Appendix A.

It is ordered:

1. Under 49 U.S.C. 10502, the Board exempts STR's construction and operation of the Line from the prior approval requirements of 49 U.S.C. 10901.

2. The Board adopts the environmental mitigation measures set forth in appendix A to this decision and imposes them as conditions to the exemption granted here.

3. Notice will be published in the **Federal Register**.

4. Petitions for reconsideration must be filed by April 22, 2024.

5. This decision is effective May 1, 2024.

Decided: April 1, 2024.

By the Board, Board Members Fuchs, Hedlund, Oberman, Primus, and Schultz. Board Member Schultz, joined by Board Member Fuchs, dissented in part with a separate expression.

Board Member Schultz, With Whom Board Member Fuchs Joins, Dissenting in Part

I join the majority's decision except for the last mitigation measure. In response to EPA's environmental comments, OEA proposed, and the Board now adopts, language stating that STR's climate change plan ''shall use'' certain CEQ guidance to achieve objectives in an executive order. I would not include that requirement as it is drafted. For one, it is vague in what it requires. Moreover, relatedly, and more importantly, its impacts are uncertain. I do not know whether guidance designed for Federal agencies should be wholesale applied to businesses; whether that guidance could be better tailored to the specifics of this particular project; or whether STR has the information that would be necessary to implement that guidance effectively. Absent more detail and more information about likely compliance strategies, including both their effectiveness and burden, I would not impose the condition in its current form.

Kenyatta Clay,

Clearance Clerk.

Appendix A

General Mitigation Measures

STR's Voluntary Mitigation Measures

VM-General–01. STR will follow all applicable Federal Occupational Safety and Health Administration, Federal Railroad Administration, and operational safety regulations to minimize the potential for accidents and incidents during project-related construction and operation.

VM-General–02. STR's contractors(s) will limit ground disturbance to only the areas necessary for project-related construction.

VM-General–03. STR's contractor(s) will stockpile excavated soil in areas away from environmentally or culturally sensitive areas and will use appropriate erosion control measures to prevent or contain erosion.

VM-General–04. STR's contractors(s) will perform finish grading and surface disturbed areas with appropriate best management practices, where practical and in consultation with the City of Erda when construction is completed.

VM-General–05. Prior to project-related construction, STR will secure agreements with utility owners to establish responsibility for protecting or relocating existing utilities, if impacted by construction.

VM-General–06. STR will appoint a liaison to consult with communities, businesses, agencies, tribal governments, educational institutions, and nonprofit organizations to provide general project information, progress on construction, information on rail operations and safety as needed and will seek to develop cooperative solutions to local concerns regarding project-related construction.

VM-General–07. STR and its contractor(s) will consult with appropriate adjacent landowners for coordination of construction schedules and temporary access during project- related construction.

VM-General–08. STR will install construction warning and detour signs throughout the corridor and at recreation sites around the project area as needed.

VM-General–09. During project-related construction activities, STR and its contractors will comply with speed limits and applicable laws and regulations when operating vehicles and equipment on public roadways.

VM-General–10. STR will design and construct any new temporary or permanent access roads and road realignments to comply with the reasonable requirements of the UDOT Roadway Design Manual (UDOT 2020), other applicable road construction guidance (*e.g.,* county road right-of-way encroachment standards), and agency or landowner requirements regarding the establishment of safe roadway conditions.

OEA's Final Recommended Mitigation

MM-General–01. If there is a material change in the facts or circumstances upon

which the Board relied in imposing specific environmental mitigation conditions, and upon petition by any party who demonstrates such material change, the Board shall consider revising its final mitigation, if warranted and appropriate.

Noise

STR's Voluntary Mitigation Measures

VM-Noise–01. STR will comply with Federal Railroad Administration regulations (49 CFR part 210) establishing decibel limits for train operation.

VM-Noise–02. STR will work with its contractor(s) to make sure that project-related construction and maintenance vehicles are maintained in good working order, with properly functioning mufflers to control noise.

VM-Noise–03. Prior to commencing construction activities STR will confer with the City of Erda, UDOT, and Tooele County about the establishment of Quiet Zones at Route 138 and Erda Way and will assist the City of Erda and Tooele County in identifying appropriate supplemental or alternative safety measures, practical operational methods, or technologies that lead to the establishment of Quiet Zones at those locations, in accordance with FRA's rules and procedures.

VM-Noise–04. During project-related construction, STR's daily construction schedule will adhere to time restrictions that limit construction noise prior to 7:00 a.m. or after 5:00 p.m. to the maximum extent practicable, with the exception of road crossing construction, which may occur on a 24/7 schedule to lessen traffic interruptions.

VM-Noise–05. Prior to project-related construction outside of local time restrictions within the city limits of the City of Erda, STR will consult with and comply with the reasonable requirements of the City of Erda for a special use permit to allow nighttime construction.

OEA's Final Recommended Mitigation

MM-Noise–01. STR shall employ reasonable and feasible noise mitigation, such as building sound insulation where OEA identified one receptor (receptor #6) that would experience noise impacts at or greater than the regulatory analytical threshold of 65 day-night average sound level (DNL)/+3 A-weighted decibels (dBA). STR shall implement the following in developing the building sound insulation:

- Using industry standard loudspeaker testing, the existing building sound insulation performance shall be determined in accordance with ASTM 966–90, *Standard Guide for Field Measurements of Airborne Sound Insulation of Building Facades and Façade Elements.*
- The design goal for the sound insulation shall be a 10 dBA noise reduction. The calculated Noise Level Reduction (NLR) improvement shall be at least 5 dBA. If the calculated NLR associated with acoustical replacement windows and doors is less than 5 dBA then no additional mitigation shall be required since the improvement would be minor and likely not noticeable. The overall goal of the required sound insulation analysis is to demonstrate that interior noise levels (with the Proposed Action) at receptor #6 would be 45 DNL or lower, and to implement sound insulation to result in an NLR improvement of 5 dBA or more, where feasible and reasonable based on the characteristics of the property.

MM-Noise–02. Because the modeled noise contour also comes close to adversely affecting several other receptors, STR shall measure train horn and wayside noise levels from actual train operations to verify the modeled noise contour location used in this Draft EA within one month of train operations reaching one roundtrip per day. STR shall take enough measurements of the actual train horn and wayside noise levels to demonstrate that Sound Exposure Level (SEL) values achieve a 90 percent confidence interval of 3 dBA or less. If the average measured SEL value is greater than the assumed 110 dBA for horn noise (measured at 100 feet), STR shall calculate the actual 65 DNL contour using the methodology in this Draft EA and comply with the mitigation in MM-Noise–01 for any newly affected receptors.

MM-Noise–03. STR shall maintain rail and rail beds according to American Railway Engineering and Maintenance-of-Way Association (AREMA) standards.

MM-Noise–04. STR shall consider lubricating curves, where doing so would both be consistent with safe and efficient operating practices and significantly reduce noise for residential or other noise sensitive receptors.

MM-Noise–05. STR shall employ safe and efficient operating procedures that, in lieu of or as a complement to other noise mitigation measures, can have the collateral benefit of effectively reducing noise from train operations. Specifically, STR shall inspect rail car wheels and maintain wheels in good working order to minimize the development of wheel flats, inspect new and existing rail for rough surfaces and, where appropriate, grind these surfaces to provide a smooth rail surface during operations, and regularly maintain locomotives.

Grade Crossing Safety and Delay

STR's Voluntary Mitigation Measures

VM-Grade Crossing–01. STR will consult with appropriate Federal, State, and local transportation agencies to determine the final design of the at-grade crossing warning devices. Warning devices on public roadways will be subject to review and approval, depending on location, by the Utah Department of Transportation, City of Erda, and Tooele County. STR will follow standard safety designs for each at-grade crossing for proposed warning devices and signs. These designs will follow the Federal Highway Administration's Manual on Uniform Traffic Control Devices for Streets and Highways (2022) and the American Railway Engineering and Maintenance-of-Way Association's guidelines for railroad warning devices. STR will also comply with applicable UDOT and local requirements.

VM-Grade Crossing–02. Prior to construction of road crossings, when reasonably practical, STR and its contractor(s) will consult with local transportation officials regarding construction phasing and temporary traffic control. STR's contractor(s) will be responsible for local agency coordination of construction schedules, detours, and temporary traffic control, as well as obtainment of necessary temporary traffic control permits from the City of Erda and Tooele County. As appropriate, STR's contractor(s) will maintain egress or traffic routing to allow for passage of emergency and other vehicles.

VM-Grade Crossing–03. Prior to project-related construction, STR will consult with UDOT and other appropriate agency(s) to determine the final details and reasonable signage for private at-grade crossings along access roads.

VM-Grade Crossing–04. Prior to project-related construction, STR will consult with UDOT and applicable road authority regarding roadway safety and user expectations, which includes items such as pavement markings, signing, delineators, and active warning devices for vehicles, pedestrians, and bicyclists at proposed at-grade crossings.

VM-Grade Crossing–05. Prior to and during project-related construction, in accordance with project plans, specifications, and permits, STR's contractor(s) will install temporary traffic control, including pavement markings, signing, and detours, throughout the project limits and applicable work zones.

VM-Grade Crossing–06. Prior to and during construction and operation of the project, STR will work with local agencies to facilitate the development of cooperative agreements with emergency service providers to share services areas and emergency call response.

VM-Grade Crossing–07. STR will consult with affected communities regarding ways to improve visibility at highway-rail at-grade crossings, including by clearing vegetation or installing lights at the crossing during construction.

M-Grade Crossing–08. STR will obtain and abide by the reasonable requirements of applicable permits and approvals for any project-related construction activities within UDOT rights-of way or State highways where UDOT has jurisdiction and off-system roads that are maintained by UDOT.

VM-Grade Crossing–09. For each of the public at-grade crossings on the proposed rail line, STR will provide and maintain permanent signs prominently displaying both a toll-free telephone number and a unique grade-crossing identification number in compliance with Federal Highway Administration regulations (23 CFR part 655). The toll-free number will enable drivers to report promptly any accidents, malfunctioning warning devices, stalled vehicles, or other dangerous conditions.

VM-Grade Crossing–10. STR will coordinate with Operation Lifesaver to provide educational programs available to communities, schools, and other organizations located along the proposed rail line. Operation Lifesaver is a nationwide, nonprofit organization that provides public education programs to help prevent collisions, injuries, and fatalities at highway/rail grade crossings.

OEA's Final Recommended Mitigation

MM-Grade Crossing–01. STR shall consult with and comply with reasonable UDOT requirements for creating new rail/roadway crossings at SR 138 and Erda Way. Specifically, STR shall abide by UDOT's reasonable requirements for new crossings under Administrative Rule R930–5, and specifically R930–5–7.6.

MM-Grade Crossing–02. STR shall not block at-grade crossings for more than 10 minutes at a time, when reasonably practical, unless mechanical failure, an obstruction on the track, or a similar emergency condition prevents a train from being moved clear of the crossing.

MM-Grade Crossing–03. STR shall notify appropriate emergency services dispatching centers if grade crossings become blocked by trains that may be unable to move for a prolonged period.

Biological Resources

OEA's Final Recommended Mitigation

MM-Biological–01. STR shall use temporary barricades, fencing, and/or flagging in habitats to contain construction related impacts to the area within the construction right-of-way. To the extent possible, staging areas shall be located in previously disturbed sites and not in habitat areas.

MM-Biological–02. STR shall limit ground disturbance to only the areas necessary for construction.

MM-Biological–03. STR shall ensure that all disturbed soils are landscaped, seeded with a native seed mix, or otherwise permanently stabilized following project-related construction.

MM-Biological–04. Prior to any project-related construction, STR shall develop and implement a mitigation plan to address the spread and control of non-native invasive plants during the construction. This plan shall address the following: (a) planned seed mixes, (b) weed prevention and eradication procedures, (c) equipment cleaning protocols, (d) revegetation methods, and (e) protocols for monitoring revegetation.

MM-Biological–05. STR shall only use herbicides in right-of-way maintenance to control vegetation that are approved by EPA and are applied by trained individuals, following the instructions on the pesticide label, who will limit application to the extent necessary for safe rail operations and not use the pesticides near wetlands. Herbicides shall be applied to prevent or minimize drift off of the right-of-way into adjacent areas.

MM-Biological–06. STR shall review updated U.S. Fish and Wildlife Service and Utah species lists prior to the start of project-related construction to see if any special status species were added after issuance of the Final EA. If new species are identified, STR shall notify OEA so that appropriate action can be taken if warranted.

MM-Biological–07. STR shall clear vegetation in preparation for construction before or after the breeding bird nesting season to avoid inadvertent removal of active nests (nesting adults, young, or eggs) and to ensure compliance with the Migratory Bird Treaty Act. If clearing is required during nesting season, STR shall consult with OEA and the local office of the U.S. Fish and Wildlife Service (USFWS) on appropriate nest survey methods for that area.

Water Resources

STR's Voluntary Mitigation Measures

VM-Water–01. STR's contractor(s) will submit a Notice of Intent to request permit coverage under Utah Pollutant Discharge Elimination System (UPDES) Construction General Permit (CGP) or Common Plan Permit (CPP) for construction stormwater management.

VM-Water–02. STR's contractor(s) will submit an application for coverage under the National Pollutant Discharge Elimination System stormwater construction permit pursuant to Section 402 of the Clean Water Act for construction stormwater management.

VM-Water–03. STR will develop a stormwater pollution prevention plan, which will include construction BMPs to control erosion and reduce the amount of sediment and pollutants entering surface waters, groundwater, and waters of the United States. STR will require its construction contractor(s) to follow all water quality control conditions identified in all permits that might be required, including the Section 404 permit from the U.S. Army Corps of Engineers (Corps) and the Section 401 Water Quality Certification from the Utah Department of Environmental Quality and the U.S. Environmental Protection Agency.

VM-Water–04. STR's contractor(s) will construct stream crossings during low-flow periods, when practical.

OEA's Final Recommended Mitigation

MM-Water–01. STR shall design drainage crossing structures for a 100-year storm event. STR shall design culverts to maintain existing surface water drainage patterns to the extent practicable and not cause or exacerbate flooding.

MM-Water–02. STR shall coordinate with the Federal Emergency Management Agency (FEMA) if construction of the culverts would result in an unavoidable increase greater than 1 foot to the 100-year water surface elevations.

MM-Water–03. STR shall obtain a permit if applicable from the U.S. Army Corps of Engineers under Section 404 of the Clean Water Act before initiating project-related construction in wetlands and other jurisdictional waters of the United States. STR shall comply with all conditions of the Section 404 permit.

MM-Water–04. STR shall minimize impacts to wetlands to the extent practicable in the final design. After all practicable steps have been taken to minimize impacts to wetlands, STR shall prepare a mitigation plan for any remaining wetland impacts in consultation with the U.S. Army Corps of Engineers, if applicable.

MM-Water–05. STR shall compensate for the loss of any wetlands through any one, or a combination of, the following purchasing credits from an authorized wetland mitigation bank, restoring a previously existing wetland or other aquatic site, enhancing an existing aquatic site's function, preserving an existing aquatic site, and/or creating a new aquatic site.

MM-Water–06. STR shall obtain a Section 401 Water Quality Certification from the Utah Department of Environmental Quality. STR shall incorporate the conditions of the Section 401 Water Quality Certification into its construction contract specifications and shall monitor the project for compliance.

Hazardous Materials

STR's Voluntary Mitigation Measures

VM-HazMat–01. Prior to initiating any project-related construction, STR's contractor(s) will prepare a hazardous waste management plan detailing the manner in which hazardous wastes will be managed and describing the types and volumes of hazardous wastes anticipated to be managed. There will be no export of hazardous materials off-site other than used rail ties. The hazardous waste management plan will address both onsite and offsite hazardous waste management and include the following: description of the methods to be used to ensure accurate piece counts or weights of shipments; waste minimization methods; facilities to be used for treatment, storage, and disposal; onsite areas designated where hazardous wastes are to be handled; identify whether transfer facilities are to be used, and if so, how the wastes will be tracked to ultimate disposal. Additionally, STR's contractor(s) will document hazardous waste inspections on a weekly basis.

VM-HazMat–02. In accordance with STR contractor(s)'s hazardous waste management plan and emergency management plan, and in the event of a spill over the applicable reportable quantity, each STR's contractor will comply with its spill prevention, control, and countermeasures plan and applicable Federal, State, and local regulations pertaining to spill containment, appropriate clean-up, and notifications.

VM-HazMat–03. STR will document all activities associated with hazardous material spill sites and hazardous waste sites and will notify the appropriate State and local agencies according to applicable regulations. The goal of the measures is to ensure the proper handling and disposal of contaminated materials, including contaminated soil, groundwater, and stormwater, if such materials are encountered. STR will use disposal methods that comply with applicable solid and hazardous water regulations.

VM-HazMat–04. STR's contractor(s) will responsibly handle and store gasoline, diesel fuel, oil, lubricants, and other petroleum products to reduce the risk of spills contaminating soils or surface waters. If a petroleum spill occurs in the project limits as a result of project-related construction, operation, or maintenance and exceeds specific quantities or enters a waterbody, STR's contractor(s) will be responsible for promptly cleaning the spill and notifying responsible agencies in accordance with Federal and State regulations.

VM-HazMat–05. STR's hazardous materials emergency response plan will address potential derailments or spills. This plan will address the requirements of the Pipeline and Hazardous Materials Safety Administration

and Federal Railroad Administration requirements for comprehensive oil spill response plans. STR will distribute the plan to Federal, State, and local emergency response agencies. This plan will include a roster of agencies and people to be contacted for specific types of emergencies during project-related construction, operation and maintenance activities, procedures to be followed by particular rail employees, emergency routes for vehicles, and the location of emergency equipment.

VM-HazMat–06. In the event of a reportable hazardous materials release, STR will notify appropriate Federal and State environmental agencies as required under Federal and State law.

VM-HazMat–07. STR will comply with applicable Federal Railroad Administration, Pipeline and Hazardous Materials Safety Administration, and Transportation Security Administration regulations for the safe and secure transportation of hazardous materials.

OEA's Final Recommended Mitigation

MM-HazMat–01. If STR encounters contamination (or signs of potential contamination) during construction activities, STR shall perform a Phase 2 environmental following American Society of Testing and Materials E1527–05, Standard Practice for Environmental Site Assessments, in addition to the Phase 1 previously performed by STR. Should findings of a Phase 2 environmental investigation identify contamination in soil and/or groundwater, STR shall coordinate with relevant State agencies on regulatory obligations and comply with those agencies' reasonable requirements for avoiding impacts related to soil and/or groundwater contamination.

Cultural Resources

OEA's Final Recommended Mitigation

MM-Cultural–01. STR shall prepare and provide to OEA a construction monitoring plan no later than 30 days prior to the start of construction and shall abide by the provisions of the plan, including any revisions by OEA, during construction activities. The plan shall address the following:

1. Training procedures to familiarize construction personnel with the identification and appropriate treatment of historic properties,

2. Monitoring of construction activities by a qualified professional archaeologist,

3. Provisions for the unanticipated discovery of archaeological sites or associated artifacts during construction activities, including procedures for notifying OEA and the Utah State Historic Preservation Officer (SHPO) or Tribal Historic Preservation Officer (THPO), pursuant to 36 CFR 800.13(b) in the event of an unanticipated discovery; and,

4. Provisions for complying with the Native American Graves Protection and Repatriation Act (25 U.S.C. 3001–3013) and other applicable Federal, State, and local laws and regulations in the event of an unanticipated discovery of unmarked human remains during construction activities.

Air Quality

STR's Voluntary Mitigation Measures

VM-Air–01. In accordance with Utah or local agency dust control permitting requirements, STR's contractor(s) will implement appropriate dust control measures to reduce fugitive dust emissions created during project-related construction. STR will require its construction contractor(s) to regularly operate water trucks on haul roads to reduce dust generation.

VM-Air–02. STR will work with its contractor(s) to make sure that construction equipment is properly maintained, and that mufflers and other required pollution-control devices are in working condition in order to limit construction-related air pollutant emissions.

Climate Change

OEA's Final Recommended Mitigation

MM-Climate–01. STR shall prepare a climate change plan documenting how the effects of climate change on rail infrastructure will be considered and addressed by STR in the final engineering design and construction of the rail line. The plan shall account for the extreme heat, drought, and wildfires that are anticipated in this region, which can cause track buckling, warping/melting, and electrical equipment disruptions. The plan shall also cover protective health and safety measures for rail personnel exposed to extreme heat. The plan shall use the Council on Environmental Quality's National Environmental Policy Act Guidance on Consideration of Greenhouse Gas Emissions and Climate Change to achieve the objectives laid out in Executive Order 14008, Tackling the Climate Crisis at Home and Abroad.

[FR Doc. 2024–07255 Filed 4–4–24; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 1339X]

Walkersville Southern Railroad, Inc.—Discontinuance of Service Exemption—in Frederick County, Md.

Walkersville Southern Railroad, Inc. (WSRR), has filed a verified notice of exemption under 49 CFR part 1152 subpart F—*Exempt Abandonments and Discontinuances of Service* to discontinue service over an approximately 2.21-mile rail line known as the Frederick Secondary Track extending between milepost 65.17, valuation station 3442+61.4 and milepost 67.38, valuation station 3560+00 north of the City of Frederick, in Frederick County, Md (the Line).[1] The Line traverses U.S. Postal Service Zip Codes 21705 and 21793.

WSRR has certified that: (1) no local traffic has moved over the Line for at least two years; (2) no overhead traffic will need to be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the Line (or a state or local government entity acting on behalf of such user) regarding cessation of service over the Line either is pending with the Surface Transportation Board or any U.S. District Court or has been decided in favor of a complainant within the two-year period; and (4) the requirements at 49 CFR 1105.12 (newspaper publication) and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the discontinuance of service shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA)[2] to subsidize continued rail service has been received, this exemption will be effective on May 5, 2024, unless stayed pending reconsideration Petitions to stay that do not involve environmental issues and formal expressions of intent to file an OFA to subsidize continued rail service under 49 CFR 1152.27(c)(2)[3] must be filed by April 15, 2024. Petitions for reconsideration must be filed by April 25, 2024.

No environmental review is required here where the underlying right-of-way was previously abandoned and where there is no indication that the discontinuance will result in potentially significant environmental impacts.[4] *See* 49 CFR 1105.6(c)(1).

[1] The Interstate Commerce Commission (ICC), the Board's predecessor, authorized WSRR to operate the Line in 1993. The Line is owned by the Maryland Transit Administration, on behalf of the State of Maryland. *See Walkersville So. R.R.—Operation Exemption—Line Owned by the State of Md.,* Docket No. FD 32329 (ICC served Sept. 30, 1993).

[2] Persons interested in submitting an OFA to subsidize continued rail service must first file a formal expression of intent to file an offer, indicating the intent to file an OFA for subsidy and demonstrating that they are preliminarily financially responsible. *See* 49 CFR 1152.27(c)(2)(i).

[3] The filing fee for OFAs can be found at 49 CFR 1002.2(f)(25).

[4] *See City of Peoria—Discontinuance of Serv. Exemption—Peoria Cnty, Ill.,* AB 1066 (Sub-No. 3X) (STB served June 5, 2023). The ICC and the parties treated the Line as abandoned when WSRR received operating authority. *See Walkersville So. R.R.—Operation Exemption—Line Owned by the State of Md.,* FD 32329, slip op. at 1 n.1 (ICC served Sept. 30, 1993).

On March 18, 2024, Frederick County, Md. (Frederick County), filed a request for a notice of interim trail use or abandonment (NITU) to negotiate with CSXT to establish interim trail use and rail banking for the Line, under the National Trails System Act, 16 U.S.C. 1247(d). Also on March 18, MTA filed a letter agreeing to negotiate with MTA toward a possible interim trail use/rail banking arrangement for the Line. Frederick County's request will be addressed in a subsequent Board decision.

All pleadings, referring to Docket No. AB 1339X, must be filed with the Surface Transportation Board via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. Additionally, a copy of each pleading filed with the Board must be sent to WSRR's representative, Wayne Kirchhof, President, Walkersville Southern Railroad, Inc., 34 West Pennsylvania Avenue, Walkersville, MD 21793.

If the verified notice contains false or misleading information, the exemption is void ab initio.

Board decisions and notices are available at *www.stb.gov.*

Decided: April 2, 2024.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Stefan Rice,

Clearance Clerk.

[FR Doc. 2024–07299 Filed 4–4–24; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 35729 (Sub-No. 1)]

Ann Arbor Railroad, Inc.—Lease Renewal and Operation Exemption With Interchange Commitment—Norfolk Southern Railway Company

Ann Arbor Railroad, Inc. (AARR), a Class III rail carrier, has filed a verified notice of exemption pursuant to 49 CFR 1150.43 to renew its lease with Norfolk Southern Railway (NSR) of rail lines totaling approximately 3.69 miles over two segments between: (1) milepost CS 1.26 and milepost CS 2.65 in Toledo, Ohio, and (2) milepost GY 85.40 and GY 87.70 in Toledo (collectively, the Lines). NSR owns the Line, and AARR currently operates the Lines under a lease.[1]

According to the verified notice, AARR and NSR have executed a first amendment to their lease, which, along with the original lease from 2013, will govern AARR's operations going forward. AARR further states it will operate the Lines and provide all rail common carrier service to shippers on the Lines as it has done since 2013.

As required under 49 CFR 1150.43(h)(1), AARR certifies in its verified notice that the lease contains an interchange commitment. AARR verifies that the terms of the interchange commitment remain the same as they were in 2013.[2] AARR has provided additional information regarding the interchange commitment as required by 49 CFR 1150.43(h).

AARR certifies that its projected revenues resulting from this transaction will not result in the creation of a Class II or Class I rail carrier but that its current annual revenue does exceed $5 million. Pursuant to 49 CFR 1150.42(e), if a carrier's projected annual revenues will exceed $5 million, it must, at least 60 days before the exemption is to become effective, post a notice of its intent to undertake the proposed transaction at the workplace of the employees on the affected lines, serve a copy of the notice on the national offices of the labor unions with employees on the affected lines, and certify to the Board that it has done so. AARR, however, has petitioned for waiver of the 60-day advance labor notice. AARR's waiver request will be addressed in a separate decision in which the Board will also establish the effective date of the exemption.

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 April 12, 2024.

All pleadings, referring to Docket No. FD 35729 (Sub-No. 1), must be filed with the Surface Transportation Board 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 AARR's representative, Robert A. Wimbish, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606–3208.

According to AARR, this action is categorically excluded from historic preservation reporting requirements under 49 CFR 1105.8(b) and from environmental reporting requirements under 49 CFR 1105.6(c).

Board decisions and notices are available at *www.stb.gov.*

Decided: April 1, 2024.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Brendetta Jones,

Clearance Clerk.

[FR Doc. 2024–07264 Filed 4–4–24; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2024–0025]

Agency Information Collection Activities: Request for Comments for a New Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: The FHWA has forwarded the information collection request described in this notice to the Office of Management and Budget (OMB) to approve a new information collection. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by May 6, 2024.

ADDRESSES: You may submit comments identified by DOT Docket ID Number 0025 by any of the following methods:

Website: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Fax: 1–202–493–2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ms. Cynthia Essenmacher, (202) 780–6178, Department of Transportation, Federal Highway Administration, Office of Operations, Office of Transportation Management (HOTM–1), 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours are from 7 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays.

[1] AARR has been authorized to lease and operate the Line since 2013. *See Ann Arbor R.R.—Norfolk S. Ry.,* FD 35729 (STB served July 12, 2013).

[2] A copy of the lease containing the interchange commitment was filed under seal with the verified notice. *See* 49 CFR 1150.43(h)(1).

SUPPLEMENTARY INFORMATION: We published a **Federal Register** notice with a 60-day public comment period on this information collection on January 24, 2024 (89 FR 4649).

Title: Innovative Finance and Equal Access for Over the Road Buses.

Background: The Federal Highway Administration (FHWA), Office of Operations and Office of the Chief Financial Officer, jointly collects information related to State Infrastructure Banks (SIB), Grant Anticipation Revenue Vehicles, and Toll Credits. This information is published on FHWA's public websites to monitor activity in each innovative finance program. This information satisfies the requirement under 23 U.S.C. 610(g)(7) for each SIB to make an annual report to the Secretary on its status no later than September 30 of each year and such other reports as the Secretary may require. The data will also satisfy new requirements under section 11503 of the Infrastructure Investment and Jobs Act (IIJA), Public Law 117–58, effective November 15, 2021, requiring the Secretary to make available a publicly accessible website on which States shall post the amount of toll credits that are available for sale or transfer.

The data includes activity, volume, and balances. The data is published annually on the Center for Innovative Finance's website. Information from this collection is used for the proper stewardship and oversight of each program, as well as compliance with each program's Federal statute.

Equal Access for Over the Road Busses: Section 11523 of the Bipartisan Infrastructure Law (BIL), enacted as the Infrastructure Investment and Jobs Act, Public Law 117–58 (Nov. 15, 2021) amended 23 U.S.C. 129 to add reporting requirements to the equal access provisions for over the road busses. Specifically, not later than 90 days after the date of enactment of the BIL, a public authority that operates a toll facility shall report to the Secretary any rates, terms, or conditions for access to the toll facility by public transportation vehicles that differ from the rates, terms, or conditions applicable to over-the-road buses.

Further, a public authority that operates a toll facility shall report to the Secretary any change to the rates, terms, or conditions for access to the toll facility by public transportation vehicles that differ from the rates, terms, or conditions applicable to over-the-road buses by not later than 30 days after the date on which the change takes effect.

Respondents: State governments of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the Northern Marianas, and the Virgin Islands share this burden.

Frequency: Annually August 1st to October 31st.

Estimated Average Burden per Response: The estimated average reporting burden per response for the annual collection and processing of the data is 55.5 hours for each of the States (including local governments), the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the Northern Marianas, and the Virgin Islands.

Estimated Total Annual Burden Hours: The estimated total annual burden for all respondents is 1164.5 hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1.48.

Issued on: April 2, 2024.

Jazmyne Lewis,

Information Collection Officer.

[FR Doc. 2024–07249 Filed 4–4–24; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA–2021–0010]

Notice of Availability of Proposed Policy Guidance for the Capital Investment Grants Program

AGENCY: Federal Transit Administration (FTA), Department of Transportation (DOT).

ACTION: Notice of availability of proposed policy guidance for the Capital Investment Grants program.

SUMMARY: The Federal Transit Administration (FTA) invites public comment on revisions to the agency's policy guidance for the Capital Investment Grants (CIG) program. These revisions are intended to amend FTA's CIG Policy Guidance last published in January 2023 and are a comprehensive update of the CIG Policy Guidance for notice and comment, incorporating feedback FTA received in response to its Request for Information published in the **Federal Register** in July 2021. The proposed guidance has been placed in the docket and posted on the FTA website. This policy guidance continues to complement FTA's regulations that govern the CIG program. FTA is also posing questions concerning the CIG New Starts and Small Starts Land Use and Economic Development Project Justification Criteria.

DATES: Comments must be received on or before June 4, 2024. Late-filed comments will be considered to the extent practicable.

ADDRESSES: You may submit comments to DOT docket number FTA–2021–0010 by any of the following methods:

Federal eRulemaking Portal: Go to *https://www.regulations.gov* and follow the online instructions for submitting comments.

U.S. Mail: Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590–0001.

Hand Delivery or Courier: U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Fax: 202–493–2251.

Instructions: You must include the agency name (Federal Transit Administration) and docket number (FTA–2021–0010) for this notice at the beginning of your comments. You must submit two copies of your comments if you submit them by mail. If you wish to receive confirmation FTA received your comments, you must include a self-addressed, stamped postcard. Due to security procedures in effect since October 2001, mail received through the U.S. Postal Service may be subject to delays. Parties submitting comments may wish to consider using an express mail firm to ensure prompt filing of any submissions not filed electronically or by hand.

All comments received will be posted, without charge and including any personal information provided, to *https://www.regulations.gov,* where they will be available to internet users. You may review DOT's complete Privacy Act Statement published in the **Federal Register** on April 11, 2000, at 65 FR 19477. For access to the docket and to

read background documents and comments received, go to *https://www.regulations.gov* at any time or to the U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Management Facility, West Building, Ground Floor, Room W12–140, Washington, DC 20590 between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Elizabeth Day, FTA Office of Planning and Environment, telephone (202) 366–5159 or *Elizabeth.Day@dot.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 49 U.S.C. 5309(g)(5), FTA is required to publish policy guidance on the CIG program each time the agency makes significant changes. Also, FTA is required to invite public comment on the guidance, and to publish its response to comments. In brief, the policy guidance that FTA periodically issues for the discretionary Capital Investment Grants (''CIG'') program complements the FTA regulations that govern the CIG program, codified at 49 CFR part 611. The regulations set forth the process that grant applicants must follow to be considered for discretionary funding under the CIG program, and the procedures and criteria FTA uses to rate and evaluate the projects to determine their eligibility for that discretionary funding. The policy guidance provides a greater level of detail about the methods FTA uses and the sequential steps a sponsor must follow in developing a project.

FTA is seeking comment on proposed changes to FTA's CIG Policy Guidance last issued in January 2023. (*https://www.transit.dot.gov/funding/grant-programs/capital-investments/final-capital-investment-grant-program-interim-policy*). The proposals cover multiple topics. The proposals being made today are available on the agency's public website at *https://www.transit.dot.gov/CIG,* and in the docket at *https://www.regulations.gov.*

FTA is also posing questions concerning the CIG New Starts and Small Starts Land Use and Economic Development Project Justification Criteria:

1. FTA currently evaluates Land Use for New Starts and Small Starts projects based primarily on station area population densities, total employment served by the project, and the percentage of ''legally binding affordability restricted'' housing within a ½ mile of station areas as compared to the counties in which the corridor is located. FTA is proposing to evaluate Land Use for New Starts and Small Starts projects based on station area population densities, total employment served by the project, the percentage of ''legally binding affordability restricted'' housing within a ½ mile of station areas, and two new quantitative measures—community risk and access to essential services. Should FTA also add a measure of walkability to the New Starts and Small Starts Land Use Criteria? If so, please identify measures/data sources that would be readily available nationwide without requiring an undue burden on project sponsors to gather and FTA to verify the information. For example, should FTA add a measure using EPA's National Walkability Index (*https://www.epa.gov/smartgrowth/national-walkability-index-user-guide-and-methodology*)?

2. For New Starts and Small Starts projects, should FTA use the US DOT Equitable Transportation Community (ETC) Explorer (*https://www.transportation.gov/priorities/equity/justice40/etc-explorer*), an interactive web application that uses census tracts and data to explore the cumulative burden communities experience as a result of underinvestment in transportation, as a measure for Land Use? If so, should this be in addition to the five measures FTA is proposing in the Policy Guidance, or as a substitute for the proposed community risk measure?

3. For New Starts and Small Starts projects, FTA currently evaluates the following under Economic Development: (1) transit-supportive plans and policies, which includes supportive zoning in station areas; (2) the performance and impacts of transit-supportive plans and policies; and (3) the tools to maintain or increase the share of affordable housing in station areas. FTA is proposing to make supportive zoning in station areas a standalone subfactor. FTA is proposing to move the other current measures of transit-supportive plans and policies (growth management (for New Starts only), transit supportive corridor policies, and tools to implement land use policies) to the subfactor performance and impacts of transit-supportive plans and policies. FTA is proposing that equal weight be given to three subfactors: supportive zoning in station areas, performance and impacts of transit-supportive plans and policies, and tools to maintain or increase the share of affordable housing in station areas, when developing the overall Economic Development rating. Should FTA do more to increase the relative weight of zoning as part of the Economic Development rating? For example, should FTA:

a. Maintain its proposal to include three subfactors within Economic Development (supportive zoning in station areas, performance and impacts of transit-supportive plans and policies, and tools to maintain or increase the share of affordable housing in station areas) but assign the zoning subfactor more weight than the other two?

b. Eliminate some of the non-zoning Economic Development subfactors or measures and if so, which ones?

c. Make any other changes to the Economic Development subfactors or measures, and if so, which ones and how?

After review and consideration of the comments provided on the proposals in this document and the answers to the questions, FTA will issue a final notice and incorporate these changes into the existing CIG Policy Guidance.

Issued under the authority delegated in 49 CFR 1.91.

Veronica Vanterpool,

Acting Administrator.

[FR Doc. 2024–07218 Filed 4–4–24; 8:45 am]

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Part II

Environmental Protection Agency

40 CFR Parts 60 and 63
National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 60 and 63

[EPA–HQ–OAR–2019–0178; FRL–7055–02–OAR]

RIN 2060–AU37

National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action finalizes the residual risk and technology review (RTR) conducted for the Commercial Sterilization Facilities source category regulated under national emission standards for hazardous air pollutants (NESHAP) under the Clean Air Act. The EPA is finalizing decisions concerning the RTR, including definitions for affected sources, emission standards for previously unregulated sources, amendments pursuant to the risk review to address ethylene oxide (EtO) emissions from certain sterilization chamber vents (SCVs), aeration room vents (ARVs), chamber exhaust vents (CEVs), and room air emissions, and amendments pursuant to the technology review for certain SCVs and ARVs. In addition, we are taking final action to correct and clarify regulatory provisions related to emissions during periods of startup, shutdown, and malfunction (SSM), including removing exemptions for periods of SSM. We are also taking final action to require owners and operators to demonstrate compliance through the use of EtO continuous emissions monitoring systems (CEMS), with exceptions for very small users of EtO; add provisions for electronic reporting of performance test results and other reports; and include other technical revisions to improve consistency and clarity. We estimate that these final amendments will reduce EtO emissions from this source category by approximately 21 tons per year (tpy).

DATES: This final rule is effective on April 5, 2024. The incorporation by reference (IBR) of certain material listed in the rule is approved by the Director of the Federal Register April 5, 2024. The incorporation by reference (IBR) of certain other material listed in the rule was approved by the Director of the Federal Register before February 27, 2021.

ADDRESSES: The U.S. Environmental Protection Agency (EPA) has established a docket for this action under Docket ID No. EPA–HQ–OAR–2019–0178. All documents in the docket are listed on the *https://www.regulations.gov/* website. Although listed, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *https://www.regulations.gov/,* or in hard copy at the EPA Docket Center, WJC West Building, Room Number 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Standard Time (EST), Monday through Friday. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact U.S. EPA, Attn: Jonathan Witt, Mail Drop: E143–05, 109 T.W. Alexander Drive, P.O. Box 12055, RTP, North Carolina 27711; telephone number: (919) 541–5645; and email address: *witt.jon@epa.gov.* For specific information regarding the risk modeling methodology, contact U.S. EPA, Attn: Matthew Woody, Mail Drop: C539–02, 109 T.W. Alexander Drive, P.O. Box 12055, RTP, North Carolina 27711; telephone number: (919) 541–1535; and email address: *woody.matt@epa.gov.*

SUPPLEMENTARY INFORMATION:

Preamble acronyms and abbreviations. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

ADAF age-dependent adjustment factor
AEGL acute exposure guideline level
APCD air pollution control device
ARV aeration room vent
ASME American Society of Mechanical Engineers
BTF Beyond-the-Floor
BMP best management practice
CAA Clean Air Act
CDX Central Data Exchange
CEDRI Compliance and Emissions Data Reporting Interface
CEMS continuous emission monitoring system
CEV chamber exhaust vent
CFR Code of Federal Regulations
cfs cubic feet per second
dscfm dry standard cubic feet per minute
EJ environmental justice
EPA Environmental Protection Agency
ERT Electronic Reporting Tool
EtO ethylene oxide
FDA Food and Drug Administration
FIFRA Federal Insecticide, Fungicide, and Rodenticide Act
FR Federal Register
FRFA final regulatory flexibility analysis
FTIR Fourier Transform Infrared Spectroscopy
GACT generally available control technology
HAP hazardous air pollutants(s)
HEM Human Exposure Model
HQ hazard quotient
ICR Information Collection Request
ID Interim Decision
IFU instructions for use
IRFA initial regulatory flexibility analysis
IRIS Integrated Risk Information System
ISO International Organization for Standardization
km kilometer
lb pound
lb/h pounds per hour
LEL lower explosive limit
LPL lower prediction limit
MACT maximum achievable control technology
MIR maximum individual risk
mg/L milligrams per liter
NAICS North American Industry Classification System
NDO natural draft opening
NESHAP national emission standards for hazardous air pollutants
OMB Office of Management and Budget
OPP Office of Pesticide Programs
OSHA Occupational Safety and Health Administration
PID Proposed Interim Decision
ppbv parts per billion by volume
ppm parts per million
ppmv parts per million by volume
PTE permanent total enclosure
REL reference exposure level
RDL Representative detection level
RFA Regulatory Flexibility Act
RIA regulatory impact assessment
RTR risk and technology review
SAB Science Advisory Board
SBA Small Business Administration
SBAR Small Business Advocacy Review
SCV sterilization chamber vent
SER small entity representative
SSM startup, shutdown, and malfunction
TOSHI target organ-specific hazard index
tpy tons per year
UPL upper prediction limit
$\mu g/m^3$ micrograms per cubic meter
UMRA Unfunded Mandates Reform Act
URE unit risk estimate
VCS voluntary consensus standards

Background information. On April 13, 2023, the EPA proposed revisions to the Commercial Sterilization Facilities NESHAP based on our RTR. In this action, we are finalizing decisions and revisions for the rule. We summarize some of the more significant comments we timely received regarding the proposed rule and provide our responses in this preamble. A summary of all other public comments on the proposal and the EPA's responses to

those comments is available in *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* Docket ID No. EPA–HQ–OAR–2019–0178. A ''track changes'' version of the regulatory language that incorporates the changes in this action is available in the docket.

Organization of this document. The information in this preamble is organized as follows:

I. General Information

A. Executive Summary

1. Purpose of the Regulatory Action

Exercising authority under multiple provisions of section 112 of the Clean Air Act (CAA), we are finalizing revisions to the NESHAP for Commercial Sterilization Facilities (40 CFR part 63, subpart O) by both amending the current standards and establishing standards for previously unregulated emissions within this source category. First, we are finalizing emission standards under CAA sections 112(d)(2)–(3) and (d)(5) for previously unregulated emission sources of EtO. Second, we are finalizing risk-based standards under CAA section 112(f)(2) to protect public health with an ample margin of safety. Third, we are finalizing emission standards under CAA section 112(d)(6) based on our review of developments in practices, processes, and control technologies for this source category.

This final rulemaking reflects the EtO toxicological assessment that EPA's Integrated Risk Information System (IRIS) Program completed in December 2016,[1] which indicated that EtO is a far more potent carcinogen than we had understood when the RTR for this source category was conducted in 2006. There are 88 commercial sterilization facilities in this source category, many of which are located near residences, schools, and other public facilities. Many of these facilities are also located in communities with environmental justice (EJ) concerns. We have determined that approximately 23 of these facilities pose high lifetime cancer risks to the surrounding communities, and some facilities pose exceptionally high risks that are among some of the highest for a CAA section 112(f)(2) risk assessment. Throughout this rulemaking process, we have engaged in outreach activities to these communities, along with their State and local governments, to discuss their concerns, along with the need and potential solutions for reducing emissions and increasing transparency on exposure and potential impacts to communities, which this final rule will achieve.

This important action will reduce EtO emissions and lifetime cancer risks in multiple communities across the country, including communities with EJ concerns, and it updates our standards using proven and cost-effective control technologies that are already in use at some facilities in this source category. The protections offered by these standards will be especially important for children. In addition, this rule will advance the President's Cancer Moonshot,[2] by preventing cancer before it starts. Recognizing that we now have additional information about the health risks of EtO that was not available at the time of the 2006 RTR, and in order to ensure that our standards for this source category adequately protect public health, we have conducted a second residual risk review under CAA section 112(f)(2), as discussed in section I.A.3 of this preamble.

In deciding to conduct this second residual risk review, we considered the health effects of EtO exposure, the impacts to surrounding communities, the advantages of EtO reductions, and the distribution of those reductions consistent with the clear goal of CAA section 112(f)(2) to protect the most exposed and susceptible populations. While commercial sterilizers provide a critical benefit for the health of all, protecting people who live near commercial sterilization facilities from the disproportionate risk of being significantly harmed by toxic air

[1] *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide,* December 2016, EPA/635/R–16/350Fc.

[2] *https://www.whitehouse.gov/briefing-room/statements-releases/2023/09/13/fact-sheet-as-part-of-president-bidens-unity-agenda-white-house-cancer-moonshot-announces-new-actions-and-commitments-to-end-cancer-as-we-know-it/.*

pollution is also a core responsibility for the EPA under the CAA.

At the same time, we recognize that commercial sterilization facilities play a vital role in maintaining an adequate supply of sterilized medical devices for public health needs in the U.S. According to the U.S. Food and Drug Administration (FDA), ''Literature shows that about fifty percent of all sterile medical devices in the U.S. are sterilized with ethylene oxide.'' FDA also notes that, ''For many medical devices, sterilization with ethylene oxide may be the only method that effectively sterilizes and does not damage the device during the sterilization process.'' [3] In developing this final rule, therefore, we carefully considered the important function these facilities serve, drawing from extensive engagement with industry stakeholders as well as Federal agencies with expertise in and responsibility for the medical device supply chain.

To ensure our actions with respect to this source category are based on the most accurate and complete information possible, we have had many interactions with the EtO commercial sterilization industry in recent years, including meetings, requests for information, and outreach specific to this final rulemaking. This has enabled us to work from the best possible information when conducting the analyses to support this final rulemaking, including the current configuration of facilities and the performance of control technologies that are currently used.

We have engaged with the U.S. Department of Health and Human Services, particularly FDA, regarding the potential impacts of this final rule on commercial facilities that sterilize medical devices. These discussions have focused on identifying and discussing any concerns regarding the potential impact on the availability of certain medical devices that are sterilized with EtO, in cases where alternative sterilization methods are not readily available, in particular, devices that are (1) experiencing or at risk of experiencing a shortage, (2) intended to provide life-supporting, life-sustaining care or that is intended for use in emergency medical care or during surgery, (3) used in pediatric services, and/or (4) sterilized exclusively at a particular facility.

Mindful of the vital role that commercial sterilizers play in supplying the nation with sterile medical devices, and the core objective of protecting public health under CAA section 112, the EPA has carefully evaluated the feasibility and cost of compliance with this rule, and potential implications for the medical device supply chain.[4] The EPA notes that a number of the facilities covered by this final rule have already implemented one or more of the controls that will be needed for compliance. Moreover, the EPA's own experience working with facility owners, as well as State and local agencies that have regulated EtO emissions from these facilities, confirms that it is feasible for individual facilities to install the required controls well within the deadlines provided in this rule, and for multiple facilities to do so simultaneously.

In addition, as a result of the comments received, as well as the EPA's consultation with FDA and other Federal partners, the final rule incorporates several key changes from the proposed rule, including modifications to the format of certain standards and compliance flexibilities. We are also providing sufficient compliance time to enable these facilities to continue sterilizing products while installing and testing new control systems and associated equipment that will afford ample protection for nearby communities. These modifications to the proposed rule are intended to facilitate cost-effective compliance, and to avoid any impacts to the integrity of the medical device supply chain, while ensuring that these standards reduce cancer risks for communities exposed to EtO emissions.

Given that key industry players are already planning for compliance, and in light of the significant changes made between the proposal and this final rule, the EPA does not anticipate that the implementation of these standards will have any adverse impacts on the medical supply chain. However, as the Agency proceeds to implement this final rule, we intend to continue to work closely with FDA, the relevant trade associations, and facility owners to monitor the process of planning for compliance, to proactively identify any anticipated changes in facility operations that might implicate the medical supply chain, and to take appropriate steps to address any such impacts. In addition, in order to increase the resilience of the medical supply chain, we support the development and implementation of viable, safe, and cost-effective alternatives to EtO sterilization.

On April 13, 2023, the Office of Pesticide Programs (OPP) published a notice announcing the availability of a proposed interim decision (PID) as part of its periodic review of the registration of EtO under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (88 FR 22447). The PID contained a number of measures aimed at protecting workers from excessive EtO exposure. Since the issuance of the PID, OPP has been actively collaborating with the Office of Air and Radiation to ensure that the requirements of the FIFRA Interim Decision (ID) do not interfere with the requirements of this rule, and vice versa. The ID will contain the final requirements to mitigate worker exposure to EtO, considering the comments received on the PID. Furthermore, OPP has been consulting regularly with other Federal agencies and with industry trade groups, to discuss how best to harmonize the requirements of the FIFRA ID with the requirements of this rule, and to ensure that the operative standards, once finalized, will protect both workers and neighboring communities from the risks of EtO exposure while mitigating and managing any risk to the supply chain for sterile medical devices.

2. Summary of the Major Provisions of the Regulatory Action in Question

We are finalizing numeric emission limits, operating limits, and management practices under CAA sections 112(d)(2)–(3), (d)(5), and (d)(6) for EtO emissions from certain emission sources, and also finalizing standards under CAA section 112(f)(2) for certain emission sources in order to ensure that the standards provide an ample margin of safety to protect public health.[5]

For the following, previously unregulated emission sources at commercial sterilization facilities, we are setting standards under CAA sections 112(d)(2)–(3) or (d)(5): SCVs and ARVs at facilities where EtO use is less than 1 tpy,[6] ARVs at facilities where

[3] *https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices.*

[4] For more information, see the document *Regulatory Impact Analysis for the Final National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations,* available in the docket for this rulemaking.

[5] In 1992, pursuant to CAA section 112(c)(1), we published a list of major and area sources for regulation under CAA section 112, including major and area sources at commercial sterilization facilities. 57 FR 31576, 31586 (July 16, 1992). Area sources at commercial sterilization facilities were listed for regulation under CAA section 112(c)(3) based on our finding that they present a threat of adverse effects to human health or the environment (by such sources individually or in the aggregate) warranting regulation under that section. Id. at 31586.

[6] In developing the original rule, EPA considered potential standards for SCV and ARV at area source facilities where EtO use is less than 1 tpy but the Agency understood these sources at the time to have low emission contributions (*e.g.,* a facility

EtO use is at least 1 tpy but less than 10 tpy,[7] CEVs,[8] and room air emissions.[9]

Next, based on our assessment of the residual risk after considering the emission reductions from the previous standards in subpart O, as well as the standards under CAA sections 112(d)(2)–(3) or (d)(5) for the previously unregulated sources, we are finalizing more stringent standards under CAA section 112(f)(2) to address risk at the following types of sources:

- SCVs at facilities where EtO use is at least 30 tpy
- SCVs at facilities where EtO use is at least 10 tpy but less than 30 tpy
- SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy
- ARVs at facilities where EtO use is at least 30 tpy
- CEVs at area source facilities [10] where EtO use is at least 400 tpy
- CEVs at area source facilities where EtO use is at least 60 but less than 400 tpy
- Group 1 room air emissions [11] at area source facilities where EtO use is at least 40 tpy
- Group 2 room air emissions [12] at area source facilities where EtO use is at least 20 tpy
- Group 2 room air emissions at area source facilities where EtO use is at least 4 tpy but less than 20 tpy

Finally, under CAA section 112(d)(6), we are revising current standards for the following sources that were regulated in the previous 40 CFR part 63, subpart O:

- SCVs at facilities where EtO use is at least 10 tpy
- SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy
- ARVs at facilities where EtO use is at least 10 tpy

Table 1 summarizes the final CAA section 112(d) and 112(f)(2) standards.

TABLE 1—SUMMARY OF STANDARDS AFTER TAKING ACTIONS PURSUANT TO CAA SECTIONS 112(d)(2), 112(d)(3), 112(d)(5), 112(f)(2), AND 112(d)(6)

Emission source	Existing or new?	EtO use	Standards	CAA section
SCV	Existing and new	At least 30 tpy	99.99 percent emission reduction	112(f)(2).
		At least 10 tpy but less than 30 tpy.	99.9 percent emission reduction	112(f)(2).
		At least 10 tpy	99.9 percent emission reduction	112(d)(6).
		At least 1 but less than 10 tpy.	99.8 percent emission reduction	112(f)(2) and 112(d)(6).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
ARV	Existing	At least 30 tpy	99.9 percent emission reduction	112(f)(2).
		At least 10 tpy but less than 30 tpy.	99.6 percent emission reduction	112(f)(2).
		At least 10 tpy	99.6 percent emission reduction	112(d)(6).
		At least 1 but less than 10 tpy.	99 percent emission reduction	112(d)(5).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
	New	At least 30 tpy	99.9 percent emission reduction	112(f)(2).
		At least 10 tpy	99.9 percent emission reduction	112(d)(6).
		At least 1 but less than 10 tpy.	99 percent emission reduction	112(d)(5).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
CEVs at major source facilities.	Existing and new	N/A	99.94 percent emission reduction [1]	112(d)(2) and 112(d)(3).
CEVs at area source facilities.	Existing and new	At least 400 tpy	99.9 percent emission reduction	112(f)(2).
		At least 60 but less than 400 tpy.	99.9 percent emission reduction	112(f)(2).
		Less than 60 tpy	99 percent emission reduction	112(d)(5).
Group 1 room air emissions at major sources.	Existing and new	N/A	97 percent emission reduction [2 3]	112(d)(2) and 112(d)(3).
Group 1 room air emissions at area sources.	Existing and new	At least 40 tpy	98 percent emission reduction [3]	112(f)(2).
		Less than 40 tpy	80 percent emission reduction [3]	112(d)(5).

with EtO use of 1,999 lb/yr would have roughly less than 167 lb/month of usage and emissions, and less than 41 lb/week usage and emissions.) At the time, EPA considered costs for monitoring, recordkeeping, and reporting under the rule. Threshold cutoffs for area sources are at the discretion of the Agency.

[7] EPA considered standards for ARV and CEV at area source facilities where EtO use is at least 1 tpy and less than 10 tpy. As noted, the Agency understood at the time that the largest emission source of EtO occurred from the SCV, and therefore finalized emission reduction standards for all SCV at facilities where EtO use is at least 1 tpy. At the time ARV sources were understood to have low emission contributions. As noted, threshold cutoffs for area sources are at the discretion of the Agency.

[8] The standards for CEVs were originally promulgated on December 6, 1994. Following promulgation of the rule, we suspended certain compliance deadlines and ultimately removed the standards for CEVs due to safety concerns. In the late 1990s, there were multiple explosions at EtO commercial sterilization facilities using oxidizers to control emissions from the CEV. For CEVs, it was determined that the primary contributing issue leading to the explosions was that EtO concentrations were above a safe level (*i.e.,* above the lower explosive limit (LEL)) within the CEV gas streams. We could not conclude at the time that the CEVs could be safely controlled, so the standards for CEVs were removed on November 2, 2001 (66 FR 55583). However, as discussed in section III.B.5 of the proposal preamble (88 FR 22790), facilities with controlled CEVs have revised their operating procedures to address the explosion issue by not exceeding 10 to 25 percent of the LEL. We have, therefore, determined that CEVs can be safely controlled.

[9] As discussed in section III.A, room air emissions include emissions resulting from indoor EtO storage, EtO dispensing, vacuum pump operation, pre-aeration handling of sterilized material, and post-aeration handling of sterilized material.

[10] As discussed in section III.B of the proposal preamble (88 FR 22790, April 13, 2023), CAA section 112(a) defines a major source as ''any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit considering controls, in the aggregate, 10 tpy or more of any HAP or 25 tpy or more of any combination of HAPs. . .''. It further defines an area source as ''any stationary source of HAPs that is not a major source''. A synthetic area source facility is one that otherwise has the potential to emit HAPs in amounts that are at or above those for major sources of HAP, but that has taken a restriction so that its potential to emit is less than the threshold amounts for major sources. Most of the EtO used at these facilities is released through SCVs and ARVs, and subpart O contains emission standards for these sources at facilities where EtO use is at least 10 tpy. Some State and local governments also regulate EtO emissions from these facilities. Based on these facts, as well as our review of the permits for these facilities, it is our understanding that all facilities that use more than 10 tpy are synthetic area sources.

[11] As discussed in section III.A, Group 1 room air emissions cover indoor EtO storage, EtO dispensing, vacuum pump operation, and pre-aeration handling of sterilized material.

[12] As discussed in section III.A, Group 2 room air emissions cover post-aeration handling of sterilized material.

TABLE 1—SUMMARY OF STANDARDS AFTER TAKING ACTIONS PURSUANT TO CAA SECTIONS 112(d)(2), 112(d)(3), 112(d)(5), 112(f)(2), AND 112(d)(6)—Continued

Emission source	Existing or new?	EtO use	Standards	CAA section
Group 2 room air emissions at major sources.	Existing and new	N/A	86 percent emission reduction[1 3]	112(d)(2) and 112(d)(3).
Group 2 room air emissions at area sources.	Existing	At least 20 tpy	98 percent emission reduction[3]	112(f)(2).
		At least 4 but less than 20 tpy.	80 percent emission reduction[3]	112(f)(2).
		Less than 4 tpy	Lower the EtO concentration within each sterilization chamber to 1 ppm before the chamber can be opened[4].	112(d)(5).
	New	At least 20 tpy	98 percent emission reduction[3]	112(f)(2).
		At least 4 but less than 20 tpy.	80 percent emission reduction[3]	112(f)(2).
		Less than 4 tpy	80 percent emission reduction[3]	112(d)(5).

[1] MACT floor.
[2] Beyond-the-Floor (BTF) standard.
[3] To assure compliance with the emission limit, we are requiring each facility to operate area sources with these emissions in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51.
[4] Owners and operators may also apply for an alternative means of emission limitation under CAA section 112(h)(3).

To demonstrate compliance with the emission limits, we are finalizing capture requirements. We are also finalizing a requirement for facilities to monitor with an EtO continuous emissions monitoring system (CEMS), with exceptions for small users.

3. EPA Authority

We note that the EPA completed a residual risk and technology review under CAA sections 112(f)(2) and 112(d)(6), respectively, for this source category in 2006 (71 FR 17712). While CAA section 112(f)(2) requires only a one-time risk review, which is to be conducted within eight years of the date the initial standards are promulgated, it does not limit our discretion or authority to conduct another risk review should we consider that such review is warranted. As discussed in more detail in section IV.C of this preamble, as our understanding of the health effects of EtO developed, we conducted a second residual risk review under CAA section 112(f)(2) for commercial sterilization facilities using EtO in order to ensure that the standards provide an ample margin of safety to protect public health.

As discussed in further detail in section IV.C, this second residual risk review also encompasses certain area sources for which we did not evaluate residual risk in our 2006 rulemaking. Although CAA section 112(f)(5) states that a risk review is not required for categories of area sources subject to generally available control technology (GACT) standards, it does not prohibit such review. In 2006, we undertook a CAA section 112(f)(2) analysis only for area source emissions standards that were issued as maximum achievable control technology (MACT) standards and exercised our discretion under CAA section 112(f)(5) not to do a CAA section 112(f)(2) analysis for those emission points for which GACT standards were established (67 FR 17715). However, as we made clear in that prior risk assessment, ''[w]e have the authority to revisit (and revise, if necessary) any rulemaking if . . . significant improvements to science [suggest that] the public is exposed to significant increases in risk as compared to the [2006 risk assessment].'' *Id.* In light of the updated IRIS cancer unit risk estimate (URE) for EtO, which is approximately 60 times greater than the value we used in our previous risk assessment, we are now exercising our discretionary authority to conduct another CAA section 112(f)(2) analysis and to include in this analysis area source commercial sterilizers using EtO for which we have promulgated, or have considered, GACT standards.

Section 112(d)(6) of the CAA requires EPA to review and revise, as necessary, standards promulgated under CAA section 112 at least every eight years, taking into account developments in practices, processes, and control technologies. We last completed this required technology review for the Ethylene Oxide Commercial Sterilization NESHAP (40 CFR 63, subpart O) in 2006. Accordingly, in this final action, we are also conducting a CAA section 112(d)(6) review of the current standards in this source category.

4. Costs and Benefits

Table 2 of this preamble summarizes the costs of this final action for 40 CFR part 63, subpart O (Ethylene Oxide Commercial Sterilization NESHAP).

TABLE 2—TOTAL CAPITAL INVESTMENT AND TOTAL ANNUAL COST

[2021$]

Requirement	Number of facilities w/costs associated with new requirements	Total capital investment	Total annual costs
Permanent total enclosure	28	$77,500,000	$8,280,000
Additional control devices	83	187,000,000	43,000,000
Monitoring and testing	89	48,100,000	19,400,000
Recordkeeping and reporting	[1] 90	.....	[2] 2,600,000
Total	[1] 90	313,000,000	74,000,000

[1] This includes the 88 facilities that are currently operating, as well as two planned facilities that are expected to start operating within the next few years.
[2] This includes $763,000 of one-time annual costs for reading the rule and developing record systems.

The capital costs for permanent total enclosure (PTE) and additional gas/solid reactors were annualized to 20 years. We estimate that these amendments will reduce EtO emissions from this source category by 21 tpy. Table 3 of this preamble summarizes the cancer risk reductions that will result from the final amendments, which are updated based on revisions made in the final rule and described in more detail in section IV.C.2.

TABLE 3—SUMMARY OF CANCER RISK REDUCTIONS

	Current cancer risks—actual emissions	Current cancer risks—allowable emissions	Cancer risks after implementation of final amendments
Maximum Individual Risk (MIR)[1]	6,000-in-1 million	8,000-in-1 million[3]	100-in-1 million.
Number of People with Cancer Risks >100-in-1 million	19,000	260,000	0.
Number of People with Cancer Risks ≥1-in-1 million	8.5 million	62 million	700,000 to 1.4 million.[2]
Estimated Annual Cancer Incidence (cases per year)	0.9	8	0.1 to 0.2.[2]

[1] The MIR or maximum individual lifetime cancer risk is defined as the increase in estimated cancer risk associated with a 70-year lifetime of continuous exposure at the highest concentration of HAP where people are likely to live.

[2] Ranges in values account for if all facilities were performing at the level of the standards (high end) to considering facilities that are currently performing better than the standards (low end).

As indicated in table 3, we project that the standards in the final rule will significantly reduce incremental lifetime cancer risks associated with emissions of EtO from this source category. We estimate that the current maximum increase in lifetime cancer risk associated with any facility in this source category is 6,000-in-1 million based on estimated actual emissions (or 8,000-in-1 million based on allowable emissions) under the existing standards, and that approximately 19,000 people are exposed to EtO from this source category at levels that would correspond to a lifetime cancer risk of greater than 100-in-1 million (which is our presumptive upper bound threshold for acceptable health risks), based on actual emissions. When considering allowable emissions, this number increases to 260,000. Under the final rule, no individual will be exposed to EtO at levels that correspond to a lifetime cancer risk of greater than 100-in-1 million, and the number of people with a potential risk of greater than or equal to 1-in-1 million will be reduced by approximately 92 percent.

See section V of this preamble for further discussion of the costs and a discussion of the benefits of the final standards. See section IV.F of this preamble for discussion of the revisions to monitoring, recordkeeping, reporting, and testing requirements. See section IV.C for a discussion of the risk assessment results.

B. Does this action apply to me?

Regulated entities. Categories and entities potentially regulated by this action are shown in table 4 of this preamble.

TABLE 4—NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS FINAL ACTION

Industrial category	NESHAP	NAICS[1] code
Surgical and Medical Instrument Manufacturing	40 CFR part 63, subpart O	339112
Surgical Appliance and Supplies Manufacturing	40 CFR part 63, subpart O	339113
Pharmaceutical Preparation Manufacturing	40 CFR part 63, subpart O	325412
Spice and Extract Manufacturing	40 CFR part 63, subpart O	311942
Dried and Dehydrated Food Manufacturing	40 CFR part 63, subpart O	311423
Packaging and Labeling Services	40 CFR part 63, subpart O	561910

[1] North American Industry Classification System.

Table 4 of this preamble is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by the final action for the source category listed. To determine whether your facility is affected, you should examine the applicability criteria in the appropriate NESHAP. If you have any questions regarding the applicability of any aspect of this NESHAP, please contact the appropriate person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this preamble.

C. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this final action will also be available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this final action at: *https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version and key technical documents at this same website.

Additional information is available on the RTR website at *https://www.epa.gov/stationary-sources-air-pollution/risk-and-technology-review-national-emissions-standards-hazardous.* This information includes an overview of the RTR program and links to project websites for the RTR source categories.

D. Judicial Review and Administrative Reconsideration

Under Clean Air Act (CAA) section 307(b)(1), judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit (the Court) by June 4, 2024. Under CAA section 307(b)(2), the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements.

Section 307(d)(7)(B) of the CAA further provides that only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised

during judicial review. This section also provides a mechanism for the EPA to reconsider the rule if the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within the period for public comment or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule. Any person seeking to make such a demonstration should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

II. Background

A. What is the statutory authority for this action?

The statutory authority for this action is provided by sections 112 and 301 of the Clean Air Act (CAA), as amended (42 U.S.C. 7401 *et seq.*). The discussion that follows identifies the relevant statutory sections and briefly explains the contours of the methodology used to implement these statutory requirements. A more comprehensive discussion appears in the document titled *CAA Section 112 Risk and Technology Reviews: Statutory Authority and Methodology,* in the docket for this rulemaking. Section 112 of the CAA establishes a two-stage regulatory process to address emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, we must identify categories of sources emitting one or more of the HAP listed in CAA section 112(b) and then promulgate technology-based NESHAP for those sources. Sources of HAP emissions are either major sources or area sources, and CAA section 112 establishes different requirements for major source standards and area source standards. ''Major sources'' are those that emit, or have the potential to emit, any single HAP at a rate of 10 tons per year (tpy) or more, or 25 tpy or more of any combination of HAP. All other sources are ''area sources.'' For major sources, these standards are commonly referred to as maximum achievable control technology (MACT) standards and must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). In developing MACT standards, CAA section 112(d)(2) directs the EPA to consider the application of measures, processes, methods, systems, or techniques, including, but not limited to, those that reduce the volume of or eliminate HAP emissions through process changes, substitution of materials, or other modifications; enclose systems or processes to eliminate emissions; collect, capture, or treat HAP when released from a process, stack, storage, or fugitive emissions point; are design, equipment, work practice, or operational standards; or any combination of the above.

For these MACT standards, the statute specifies certain minimum stringency requirements, which are referred to as MACT floor requirements, and which may not be based on cost considerations. See CAA section 112(d)(3). For new sources, the MACT floor cannot be less stringent than the emission control achieved in practice by the best-controlled similar source. The MACT standards for existing sources can be less stringent than floors for new sources, but they cannot be less stringent than the average emission limitation achieved by the best-performing 12 percent of existing sources in the category or subcategory (or the best-performing five sources for categories or subcategories with fewer than 30 sources). In developing MACT standards, we must also consider control options that are more stringent than the floor under CAA section 112(d)(2). We may establish standards more stringent than the floor, based on the consideration of the cost of achieving the emissions reductions, any non-air quality health and environmental impacts, and energy requirements. For area sources, CAA section 112(d)(5) allows the EPA to set standards based on GACT in lieu of MACT standards. For categories of major sources and any area source categories subject to MACT standards, the second stage in standard-setting focuses on identifying and addressing any remaining (*i.e.,* ''residual'') risk pursuant to CAA section 112(f). Section 112(f) specifically states that the EPA ''shall not be required'' to conduct risk review under this subsection for categories of area sources subject to GACT standards but does not limit the EPA's authority or discretion from conducting such review. As discussed in more detail in section III.C of this preamble, in light of the updated URE regarding EtO, the EPA is choosing to exercise that discretion.

In the second stage of the regulatory process, the CAA requires the EPA to undertake two different analyses, which we refer to as the technology review and the residual risk review. Under the technology review, we must review the technology-based standards and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less frequently than every 8 years, pursuant to CAA section 112(d)(6). In conducting this review, the EPA is not required to recalculate the MACT floors that were established in earlier rulemakings. *Natural Resources Defense Council (NRDC)* v. *EPA,* 529 F.3d 1077, 1084 (D.C. Cir. 2008). *Association of Battery Recyclers, Inc.* v. *EPA,* 716 F.3d 667 (D.C. Cir. 2013). The EPA may consider cost in deciding whether to revise the standards pursuant to CAA section 112(d)(6). The EPA is required to address regulatory gaps, such as missing standards for listed air toxics known to be emitted from the source category, and any new MACT standards must be established under CAA sections 112(d)(2) and (3), or, in specific circumstances, CAA sections 112(d)(4) or (h). *Louisiana Environmental Action Network (LEAN)* v. *EPA,* 955 F.3d 1088 (D.C. Cir. 2020).

The residual risk review in the second stage of the regulatory process focuses on identifying and addressing any remaining (*i.e.,* ''residual'') risk pursuant to CAA section 112(f). For source categories subject to MACT standards, section 112(f)(2) of the CAA requires the EPA to determine whether promulgation of additional standards is needed to provide an ample margin of safety to protect public health or to prevent an adverse environmental effect. Section 112(d)(5) of the CAA provides that this residual risk review is not required for categories of area sources subject to GACT standards. Section 112(f)(2)(B) of the CAA further expressly preserves the EPA's use of the two-step approach for developing standards to address any residual risk and the Agency's interpretation of ''ample margin of safety'' developed in the *National Emissions Standards for Hazardous Air Pollutants: Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants* (Benzene NESHAP) (54 FR 38044, September 14, 1989). The EPA notified Congress in the Residual Risk Report that the Agency intended to use the Benzene NESHAP approach in making CAA section 112(f) residual risk

determinations (EPA–453/R–99–001, p. ES–11). The EPA subsequently adopted this approach in its residual risk determinations, and the United States Court of Appeals for the District of Columbia Circuit upheld the EPA's interpretation that CAA section 112(f)(2) incorporates the approach established in the Benzene NESHAP. *See NRDC* v. *EPA,* 529 F.3d 1077, 1083 (D.C. Cir. 2008).

The approach incorporated into the CAA and used by the EPA to evaluate residual risk and to develop standards under CAA section 112(f)(2) is a two-step approach. In the first step, the EPA determines whether risks are acceptable. This determination ''considers all health information, including risk estimation uncertainty, and includes a presumptive limit on maximum individual lifetime [cancer] risk (MIR) [13] of approximately 1-in-10 thousand.'' (54 FR 38045). If risks are unacceptable, the EPA must determine the emissions standards necessary to reduce risk to an acceptable level without considering costs. In the second step of the approach, the EPA considers whether the emissions standards provide an ample margin of safety to protect public health ''in consideration of all health information, including the number of persons at risk levels higher than approximately 1-in-1 million, as well as other relevant factors, including costs and economic impacts, technological feasibility, and other factors relevant to each particular decision.'' *Id.* The EPA must promulgate emission standards necessary to provide an ample margin of safety to protect public health or determine that the standards being reviewed provide an ample margin of safety without any revisions. After conducting the ample margin of safety analysis, we consider whether a more stringent standard is necessary to prevent an adverse environmental effect, taking into consideration costs, energy, safety, and other relevant factors. For more information on the statutory authority for this rule, see 88 FR 22790, April 13, 2023.

B. What is the Commercial Sterilization Facilities source category and how does the NESHAP regulate HAP emissions from the source category?

The EPA promulgated the EtO Commercial Sterilization Facilities NESHAP on December 6, 1994 (59 FR 62585). The standards are codified at 40 CFR part 63, subpart O. The EtO commercial sterilization industry consists of facilities operating a sterilizer process that uses EtO to sterilize or fumigate materials (*e.g.,* medical equipment and supplies, spices, and other miscellaneous products and items). The source category covered by this MACT standard currently includes 88 facilities.

The original 1994 rulemaking for this source category set standards for EtO emissions originating from three emission points: sterilization chamber vents (SCV), aeration room vents (ARV), and chamber exhaust vents (CEV). The SCV evacuates EtO from the sterilization chamber following sterilization, fumigation, and any subsequent gas washes before the chamber door is opened. The ARV evacuates EtO-laden air from the aeration room or chamber that is used to facilitate off-gassing of the sterile product and packaging. The CEV evacuates EtO-laden air from the sterilization chamber after the chamber door is opened for product unloading following the completion of sterilization and associated gas washes. Other sources of emissions within this source category are room air emissions from equipment used to charge EtO into sterilization chambers, as well as EtO residuals desorbing from sterilized products within the facility, but the current EtO Commercial Sterilization NESHAP does not include standards for room air emissions.

In the chamber EtO sterilization process, items to be sterilized are placed in a chamber and exposed to EtO gas at a predetermined concentration, temperature, humidity, and pressure for a period of time known as the dwell period. Following the dwell period, the EtO gas is evacuated from the chamber, and the sterilized materials are then aerated to remove EtO residuals from the product. After the aeration step, sterilized materials are typically moved to a shipping/warehouse area for storage until they are ready to be distributed to the customer. Sterilizer process equipment and emission control configurations vary across facilities. The most common sterilizer process equipment configuration includes a separate sterilizer chamber, separate aeration room, and chamber exhaust on the sterilizer chamber (also referred to as a back-vent). Another common configuration includes a combination sterilizer where the sterilization and aeration steps of the process occur within the same chamber.

Another EtO sterilization process is single-item sterilization where small individual items are sterilized in sealed pouches. EtO gas is introduced into the sealed pouch, either by injection or use of an EtO ampule, and the sealed pouch is then placed in a chamber where the sterilization step and aeration step occur.

In 2006, we finalized a residual risk review and a technology review under CAA section 112(f)(2) and CAA section 112(d)(6), respectively (71 FR 17712, April 7, 2006). No changes were made to the EtO Commercial Sterilization NESHAP in that action.

The current emission standards for commercial sterilization facilities in 40 CFR part 63, subpart O are shown in table 5:

TABLE 5—CURRENT ETO STANDARDS FOR COMMERCIAL STERILIZERS

Existing and new sources subcategory (in any consecutive 12-month period) [1]	Sterilization chamber vent (SCV)	Aeration room vent (ARV)	Chamber exhaust vent (CEV) [2]
Sources using 10 tons or more of EtO ..	99 percent emission reduction (see 40 CFR 63.362(c)).	1 part per million (ppm) maximum outlet concentration or 99 percent emission reduction (see 40 CFR 63.362(d)).	No control.
Sources using 1 ton or more of EtO but less than 10 tons of EtO.	99 percent emission reduction (see 40 CFR 63.362(c)).	No control	No control.
Sources using less than 1 ton of EtO ...	No control required; minimal record-keeping requirements apply (see 40 CFR 63.367(c)).).	No control required; minimal record-keeping requirements apply (see 40 CFR 63.367(c)).).	No control required; minimal record-keeping requirements apply (see 40 CFR 63.367(c)).).

[1] Determined on a rolling 12-month basis.

[2] The CEV emission source was included in the original standard but was later eliminated from the 40 CFR part 63, subpart O regulation in 2001.

[13] Although defined as ''maximum individual risk,'' MIR refers only to cancer risk and reflects the estimated risk if an individual were exposed to the maximum level of a pollutant for a 70-year lifetime.

For more information on the commercial sterilization industry and the current standards under 40 CFR part 63, subpart O, see 88 FR 22790, April 13, 2023.

We note that hospital sterilizers are regulated under a different NESHAP (40 CFR part 63, subpart WWWWW), which is not addressed in this rulemaking.[14] We are aware of the potential risk posed by EtO emissions from this source category and will address hospital sterilizers in a future rulemaking.

C. What changes did we propose for the Commercial Sterilization Facilities source category in our April 13, 2023, RTR proposal?

On April 13, 2023, the EPA published a proposed rule in the **Federal Register** for the EtO Commercial Sterilization NESHAP, 40 CFR part 63, subpart O, that took into consideration the RTR analyses. In the proposed rule, we proposed emission standards under CAA sections 112(d)(2)–(3) or (d)(5) for a number of unregulated emission sources of EtO. We then proposed tightening certain of these proposed standards and existing standards with risk-based standards under CAA section 112(f)(2) in order to protect public health with an ample margin of safety. Finally, we proposed revisions to certain existing standards under CAA section 112(d)(6) based on our review of developments in practices, processes, and control technologies for this source category.

For the following emission sources that were unregulated, we proposed to set standards under CAA sections 112(d)(2)–(3) or (d)(5):

- SCVs, ARVs, and CEVs at facilities where EtO use is less than 1 tpy,
- ARVs and CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy,
- CEVs at facilities where EtO use is at least 10 tpy, and
- Room air emissions.

Next, based on our assessment of the residual risk after considering the emission reductions from the standards in subpart O, as well as the proposed standards for the unregulated sources, we proposed more stringent standards under CAA section 112(f)(2) to address risk for the following types of sources:

- SCVs at facilities where EtO use is at least 40 tpy,
- SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy,
- SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, and
- Group 2 room air emissions at area source facilities where EtO use is at least 20 tpy.

Finally, under CAA section 112(d)(6), we proposed to revise standards for the following sources that were regulated in the previous 40 CFR part 63, subpart O:

- SCVs at facilities where EtO use is at least 10 tpy,
- SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, and
- ARVs at facilities where EtO use is at least 10 tpy.

Table 6 summarizes the proposed section CAA section 112(d) and 112(f)(2) standards.

TABLE 6—SUMMARY OF STANDARDS AFTER PROPOSED ACTIONS PURSUANT TO CAA SECTIONS 112(d)(2), 112(d)(3), 112(d)(5), 112(f)(2), AND 112(d)(6)

Emission source	Existing or new?	EtO use	Standards	CAA section
SCV	Existing and new	At least 40 tpy	99.94 percent emission reduction	112(f)(2).
		At least 10 tpy but less than 40 tpy.	99.94 percent emission reduction	112(f)(2).
		At least 10 tpy	99.94 percent emission reduction	112(d)(6).
		At least 1 but less than 10 tpy.	99.8 percent emission reduction	112(f)(2) and 112(d)(6).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
ARV	Existing	At least 10 tpy	99.6 percent emission reduction	112(d)(6).
		At least 1 but less than 10 tpy.	99 percent emission reduction	112(d)(5).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
	New	At least 10 tpy	99.9 percent emission reduction	112(d)(6).
		At least 1 but less than 10 tpy.	99 percent emission reduction	112(d)(5).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
CEV	Existing and new	At least 10 tpy	3.2E–4 lb/h	112(d)(2) and (3).
		At least 1 but less than 10 tpy.	99.9 percent emission reduction	112(d)(5).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
Group 1 room air emissions.	Existing and new	N/A	1.3E–3 lb/h [1]	112(d)(2) and 112(d)(3).
Group 1 room air emissions at area sources.	Existing and new	N/A	1.3E–3 lb/h [1]	112(d)(5).
Group 2 room air emissions at major sources.	Existing and new	N/A	2.8E–3 lb/h [1]	112(d)(2) and 112(d)(3).
Group 2 room air emissions at area sources.	Existing	At least 20 tpy	2.8E–3 lb/h [1]	112(f)(2).
		Less than 20 tpy	Follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 (July 15, 2014) and ISO 11138–1:2017 (March 2017).	112(d)(5).

[14] Hospitals are defined at 40 CFR 63.10448 to mean facilities that provide medical care and treatment for patients who are acutely ill or chronically ill on an inpatient basis under supervision of licensed physicians and under nursing care offered 24 hours per day. Hospitals include diagnostic and major surgery facilities but exclude doctor's offices, clinics, or other facilities whose primary purpose is to provide medical services to humans or animals on an outpatient basis.

TABLE 6—SUMMARY OF STANDARDS AFTER PROPOSED ACTIONS PURSUANT TO CAA SECTIONS 112(d)(2), 112(d)(3), 112(d)(5), 112(f)(2), AND 112(d)(6)—Continued

Emission source	Existing or new?	EtO use	Standards	CAA section
	New	N/A	2.8E–3 lb/h [1]	112(d)(5).

[1] To assure compliance with the emission limit, we proposed requiring each facility to operate areas with these emissions in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51.

To demonstrate compliance with the emission limits, we proposed capture requirements. We also proposed that facilities either monitor with an EtO CEMS or conduct initial and annual performance tests with continuous parameter monitoring.

We also proposed the following amendments:

- Corrections and clarifications to regulatory provisions related to emissions during periods of SSM, including removing general exemptions for periods of SSM and adding work practice standards for periods of SSM where appropriate.
- Revisions to monitoring and performance testing requirements and addition of provisions for electronic reporting of performance test results and reports, performance evaluation reports, and compliance reports.
- Requiring all area source facilities to obtain a title V operating permit, and
- Compliance requirements for facilities using combined emission streams.

III. What is included in this final rule?

This action finalizes the EPA's determinations pursuant to the RTR provisions of CAA section 112 for the Commercial Sterilization Facilities source category and amends the EtO Commercial Sterilization NESHAP based on those determinations. This action also finalizes other changes to the NESHAP, including adding requirements and clarifications for periods of SSM; requiring the use of CEMS to demonstrate compliance for facilities where EtO use is at least 100 pounds (lb)/year; adding provisions for electronic reporting of performance test results and reports, performance evaluation reports, and compliance reports; and other minor editorial and technical changes. This action also reflects several changes to the April 2023 proposal in consideration of comments received during the public comment period described in section IV of this preamble.

A. What are the final rule amendments addressing the affected source definitions?

The previous subpart O did not contain definitions for affected sources, which meant that the definition of an ''affected source'' at 40 CFR 63.2 applied.[15] We did not believe that this was appropriate because a facility may not route all emissions from a particular type of point source to the same control system, thus making compliance demonstration with the standards difficult. For SCVs, ARVs, and CEVs, we are finalizing, as proposed, the affected source definition as the individual vent. For Group 1 and Group 2 room air emissions, we are finalizing, as proposed, the affected source definition as the collection of all room air emissions for each group at any sterilization facility. *Group 1 room air emissions* are defined as emissions from indoor EtO storage, EtO dispensing, vacuum pump operations, and pre-aeration handling of sterilized material. *Group 2 room air emissions* are defined as emissions from post-aeration handling of sterilized material.

Section IV.A.3 of this preamble provides a summary of key comments we received on the affected source definitions and our responses.

B. What are the final rule amendments pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) for the Commercial Sterilization Facilities source category?

We are finalizing EtO emissions standards pursuant to CAA sections 112(d)(2)–(3) and 112(d)(5) for major and area sources that were previously unregulated. Please note that the final standards for some of these sources are further tightened pursuant to CAA section 112(f)(2), as shown in table 1 in section I.A above and discussed in more detail below in sections III.C and IV.[16]

Pursuant to CAA section 112(d)(2)–(3) or 112(d)(5), we are establishing in this final rule the following emission standards for the previously unregulated sources:

- 99 percent reduction for new and existing SCVs at facilities where EtO use is less than 1 tpy,
- 99 percent reduction for new and existing ARVs facilities where EtO use is at least 1 tpy less than 10 tpy,
- 99 percent reduction for new and existing ARVs at facilities where EtO use is less than 1 tpy,
- 99.94 percent reduction for new and existing CEVs at major source facilities,
- 99 percent emission reduction for new and existing CEVs at area source facilities,
- 97 percent reduction for new and existing Group 1 room air emissions at major source facilities,
- 80 percent emission reduction for new and existing Group 1 room air emissions at area source facilities,
- 86 percent reduction for new and existing Group 2 room air emissions at major source facilities, and
- 80 percent emission reduction for new Group 2 room air emissions at area source facilities.

As discussed in more detail below in section IV.C.3 of this notice, we are not finalizing any of the alternative emission limits for percent reduction standards on which we had solicited comment as part of the proposed rulemaking. Further, based on comments received on the proposed rulemaking, we are finalizing a revised best management practice (BMP) as the GACT standard under CAA section 112(d)(5) for existing Group 2 room air emissions at area sources. The BMP requires the in-chamber EtO concentration to be lowered to 1 part per million (ppm) before the chamber can be opened, as opposed to the proposed measure that would have required these facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with International Organization for Standardization (ISO) 11135:2014 and ISO 11138–1:2017. In addition, we are finalizing, as proposed, a requirement that facilities operate all areas with room air emissions subject to an emission standard in accordance with the PTE requirements of EPA

[15] 40 CFR 63.2 defines an affected source as ''the collection of equipment, activities, or both within a single contiguous area and under common control that is included in a section 112(c) source category or subcategory for which a section 112(d) standard or other relevant standard is established pursuant to section 112 of the Act.''

[16] These sources include CEVs at area source facilities where EtO use is at least 60 tpy, Group 1 room air emissions at area source facilities where EtO use is at least 40 tpy, and Group 2 room air emissions at area source facilities where EtO use is at least 4 tpy.

Method 204, irrespective of which CAA section 112 authority is invoked. Lastly, we are finalizing the removal of the 1 ppm alternative for ARVs at facilities where EtO use is at least 10 tpy. Section IV.B of this preamble provides in more detail the standards we are finalizing pursuant to CAA section 112(d)(2), 112(d)(3), and 112(d)(5), our rationales for the final standards and for changes since proposal, and a summary of key comments we received on the proposed standards and our responses.

C. What are the final rule amendments based on the risk review for the Commercial Sterilization Facilities source category?

This section introduces the final amendments to the Commercial Sterilization Facilities NESHAP being promulgated pursuant to CAA section 112(f). As in the proposal, we determined that the risks for this source category were unacceptable under the previous provisions, and we are making a final determination of unacceptability as part of this final action, warranting necessary emission reductions as directed under the provisions we are finalizing pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) in this rulemaking. When risks are unacceptable after considering the emission reductions from the standards in subpart O, we must determine the emissions standards necessary to reduce risk to an acceptable level. As such, we are promulgating final amendments to the Commercial Sterilization Facilities NESHAP pursuant to CAA section 112(f)(2) that will reduce risk to an acceptable level and will also provide an ample margin of safety to protect public health (see section IV.C of the preamble for further discussion). Based on comments received during the proposed rulemaking, we are finalizing the following EtO emissions standards under CAA section 112(f)(2):

- 99.99 percent reduction for SCVs at facilities where EtO use is at least 30 tpy,
- 99.9 percent reduction for SCVs at facilities where EtO use is at least 10 tpy but less than 30 tpy,
- 99.8 percent reduction for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy,
- 99.9 percent reduction for ARVs at facilities where EtO use is at least 30 tpy,
- 99.9 percent reduction for CEVs at area source facilities where EtO use is at least 60 tpy,
- 98 percent reduction for Group 1 room air emissions at area sources facilities where EtO use is at least 40 tpy,
- 98 percent reduction for Group 2 room air emissions at area sources facilities where EtO use is at least 20 tpy, and
- 80 percent reduction for Group 2 room air emissions at area source facilities where EtO use is at least 4 tpy but less than 20 tpy.

We are not finalizing alternative emission limits for percent reduction standards for the same reasons discussed in section III.B of this preamble. Further, based on comments received during the proposed rulemaking, we are not finalizing any of the work practice standards that were proposed for facilities where the MIR remained greater than 100-in-1 million after the imposition of requirements under ''Control Option 1''.[17] These standards would have required facilities to limit their Group 2 room air emissions to a maximum volumetric flow rate of 2,900 dry standard cubic feet per minute (dscfm) and a maximum EtO concentration of 30 parts-per-billion by volume (ppbv).

Section IV.C.3 of this preamble provides a summary of key comments we received regarding the risk review and our responses.

D. What are the final rule amendments based on the technology review for the Commercial Sterilization Facilities source category?

We determined that there are developments in practices, processes, and control technologies that warrant revisions to the previous standards for this source category. Therefore, to satisfy the requirements of CAA section 112(d)(6), we are revising the standards to include, as in the proposed rule:

- 99.8 percent reduction for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy,
- 99.6 percent reduction for existing ARVs at facilities where EtO use is at least 10 tpy, and
- 99.9 percent reduction for new ARVs at facilities where EtO use is at least 10 tpy.

Based on comments received during the proposed rulemaking, we are finalizing a 99.9 percent emission reduction standard for SCVs at facilities where EtO use is at least 10 tpy, which is different from the 99.94 percent emission reduction standard that was proposed (see section IV.D.3.a of this document for further discussion). We are not finalizing any of the alternative emission limits for percent reduction standards that we had solicited comment on as part of the proposed rulemaking. As part of the technology review, we also identified regulatory gaps (previously unregulated processes or pollutants) and are establishing new standards to fill those gaps as described in section III.B of this preamble. Section IV.D.3 of this preamble provides a summary of key comments we received regarding the technology review and our responses.

E. What are the final rule amendments addressing emissions during periods of startup, shutdown, and malfunction?

In its 2008 decision in *Sierra Club* v. *EPA, 551 F.3d 1019* (D.C. Cir. 2008), the United States Court of Appeals for the District of Columbia Circuit vacated portions of two provisions in our CAA section 112 regulations governing the emissions of HAP during periods of SSM. Specifically, the court vacated the SSM exemption contained in 40 CFR 63.6(f)(1) and 40 CFR 63.6(h)(1), holding that under section 302(k) of the CAA, emissions standards or limitations must be continuous in nature and that the SSM exemption violates the CAA's requirement that some section 112 standards apply continuously. We have eliminated the SSM exemption in this rule. Consistent with *Sierra Club* v. *EPA,* the EPA has established standards in this rule that apply at all times. We have also revised table 6 in subpart O (the General Provisions Applicability Table) in several respects as is explained in section III.G.1 of the proposal preamble (88 FR 22790). For example, we have eliminated and revised certain recordkeeping that is related to the SSM exemption as described in detail in the proposed rule and summarized again in section IV.E.1 of this preamble.

In establishing standards in this rule, we have considered startup and shutdown periods and, for the reasons explained in section III.G.1 of the proposal preamble and section IV.E of this preamble, have not established alternate standards for those periods.

The EPA is also finalizing provisions related to malfunctions as proposed. Periods of startup, normal operations, and shutdown are all predictable and routine aspects of a source's operations. Malfunctions, in contrast, are neither predictable nor routine. Instead, they are, by definition, sudden, infrequent, and not reasonably preventable failures of emissions control, process, or monitoring equipment. (40 CFR 63.2) (Definition of malfunction). The EPA interprets CAA section 112 as not requiring emissions that occur during periods of malfunction to be factored into development of CAA section 112

[17] Refer to section III.D.1.b of the proposal preamble (88 FR 22790, April 13, 2023) for further discussion of Control Option 1.

standards. This reading has been upheld as reasonable by the D.C. Circuit in *U.S. Sugar Corp.* v. *EPA,* 830 F.3d 579, 606–610 (2016).

Section IV.E.3 of this preamble provides a summary of key comments we received on the SSM provisions and our responses.

F. What other changes have been made to the NESHAP?

This rule also finalizes, as proposed, revisions to several other requirements in the Commercial Sterilization Facilities NESHAP. We describe these revisions in this section as well as other proposed provisions that have changed since proposal.

1. Demonstrating Compliance

In the majority of instances, parametric monitoring is used to good effect as an ongoing means of ensuring that these devices continue to get necessary emission reductions.[18] However, given the nature of EtO, in which small amounts can have large risk impacts, parametric monitoring alone will not be sensitive enough to detect very small fluctuations in EtO concentration. Based on comments received during the proposed rulemaking, the EPA is finalizing a requirement to use EtO CEMS for demonstrating compliance. However, facilities where EtO use is less than 100 lb/year will have the option to use EtO CEMS or performance testing and parametric monitoring to demonstrate compliance. Based on comments received during the proposed rulemaking, we are promulgating the following requirements:

- Quarterly reporting of EtO CEMS data,
- Minimum data availability of 90 percent for EtO CEMS, and
- Use of either outlet volumetric flow rate monitors or differential pressure monitors to demonstrate continuous compliance with EPA Method 204.

Based on comments received during the proposed rulemaking, we are not finalizing a requirement for the mass of EtO being routed to a control device from an SCV to be determined through inlet testing. Based on comments received during the proposed rulemaking, we are finalizing revisions to parametric monitoring requirements, and we are finalizing technical edits to Performance Specification 19 and QA Procedure 7.

2. Electronic Reporting

To increase the ease and efficiency of data submittal and data accessibility, we are finalizing, as proposed, a requirement that owners or operators of commercial sterilization facilities submit compliance reports (being finalized at 40 CFR 63.366(b) and (c)), performance test reports (being finalized at 40 CFR 63.366(f)), and performance evaluation reports (being finalized at 40 CFR 63.366(g)) electronically through the EPA's Central Data Exchange (CDX) using the Compliance and Emissions Data Reporting Interface (CEDRI). The final rule requires that performance test results collected using test methods that are supported by the EPA's Electronic Reporting Tool (ERT) as listed on the ERT website [19] at the time of the test be submitted in the format generated through the use of the ERT and that other performance test results be submitted in portable document format (PDF) using the attachment module of the ERT. Similarly, performance evaluation results of CEMS measuring relative accuracy test audit pollutants that are supported by the ERT at the time of the test must be submitted in the format generated through the use of the ERT and other performance evaluation results be submitted in PDF using the attachment module of the ERT. For compliance reports, the final rule requires that owners or operators use the appropriate spreadsheet template to submit information to CEDRI. The final version of the template for these reports is in the docket and will be located on the CEDRI website.[20] Furthermore, we are finalizing as proposed provisions that allow facility operators the ability to seek extensions for submitting electronic reports for circumstances beyond the control of the facility, *i.e.,* for a possible outage in the CDX or CEDRI or for a force majeure event in the time just prior to a report's due date, as well as the process to seek such an extension.

For a more detailed discussion of these final amendments to the Commercial Sterilization Facilities NESHAP, see section IV.G.2.g of the proposal preamble (88 FR 22790, April 13, 2023), as well as section VI.B below on compliance with the Paperwork Reduction Act. For a more thorough discussion of electronic reporting, see the memorandum, *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules,* which is available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2019–0178–0398).

3. Title V Permitting

Because of the lack of other Federal requirements under the CAA that commercial sterilization facilities are subject to, as well as the robust monitoring and reporting requirements of the final rule, we are not finalizing a requirement for area source facilities subject to subpart O to obtain a title V permit from the delegated authority in which the source is located.

4. Combined Emission Streams

To increase the ease and efficiency of complying with the revised NESHAP, we are finalizing, based on comments received during the proposed rulemaking, alternative compliance approaches for combined emission streams. For these streams, facilities will now be allowed to demonstrate compliance with a mass emission limit that is determined based on the emission standards to which the component streams are subject, as well as characteristics specific to those facilities. In addition, we are finalizing an option for owners and operators to demonstrate compliance with a site-wide emission limitation, as opposed to demonstrating compliance for each individual and combined emission stream.

5. Minor Clarifications and Corrections

We are including several additional minor clarifying edits in the final rule based on comments received during the public comment period. The comments and our specific responses to these items can be found in the document, *Summary of Public Comments and Responses for the 2024 Risk and Technology Review for Commercial Sterilization Facilities,* available in the docket for this rulemaking.

G. What are the effective and compliance dates of the standards?

The revisions to the standards being promulgated in this action are effective on April 5, 2024. The compliance date for the standards promulgated pursuant to CAA section 112(f)(2) for the following existing sources is April 6, 2026:

- SCVs at facilities where EtO use is at least 1 tpy,
- ARVs at facilities where EtO use is at least 30 tpy,

[18] Parametric monitoring is an approach that measures one or more key indicators of process operation or emission control device operation, typically on a continuous basis. The parameters are known to affect emission levels associated with the process or the control efficiency of the source's air pollution control device.

[19] *https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert.*

[20] *https://www.epa.gov/electronic-reporting-air-emissions/cedri.*

- CEVs at area source facilities where EtO use is at least 60 tpy,
- Group 1 room air emissions at area source facilities where EtO use is at least 40 tpy, and
- Group 2 room air emissions at area source facilities where EtO use is at least 4 tpy.

The compliance date for the standards promulgated pursuant to CAA section 112(d)(2)–(3), 112(d)(5) or 112(d)(6) for the following existing sources is April 5, 2027:

- SCVs at facilities where EtO use is less than 1 tpy,
- ARVs at facilities where EtO use is less than 30 tpy,
- CEVs at major source facilities,
- CEVs at area source facilities where EtO use is less than 60 tpy,
- Room air emissions at major source facilities,
- Group 1 room air emissions at area source facilities where EtO use is less than 40 tpy, and
- Group 2 room air emissions at area source facilities where EtO use is less than 4 tpy.

As required by CAA section 112(i)(1), new sources must comply with each applicable standard immediately upon its effective date, which is April 5, 2024, or upon startup, whichever is later.

The compliance schedules for existing sources have changed since proposal. We had proposed an 18-months compliance deadline for all of the proposed standards for existing sources. Based on the comments received, we have determined that 18 months is not a sufficient period for sources to comply with the CAA section 112(d)(2)–(3), 112(d)(5) and 112(d)(6) standards for existing sources, for the following reasons:

- Most commercial sterilization facilities were not initially designed to be compliant with the PTE requirements of EPA Method 204. We have learned from the comments received that for these facilities, the capture requirements associated with the emission reduction standards for Group 1 and Group 2 room air emissions in the final rule will likely require a redesign of a portion if not all of the facility. Many facilities will also need to purchase additional equipment (*e.g.,* fans, transformers, variable frequency drives, etc.) to meet the capture requirements. Moreover, compliance with the final emission standards will likely require the installation of additional control devices. We have reviewed the time that it has taken for previous projects of this nature to be completed, from submission of the initial State or local permit application to installation of the continuous compliance mechanisms. Based on this analysis, we find that the process of bringing a facility into compliance with the PTE requirements of EPA Method 204, as well as installing and verifying additional emission controls, can take approximately a year from permit submission to project completion. However, this estimate does not account for the time needed to design and plan before the initial permit application is submitted, nor for the time needed to avoid impacts on medical device supply chains, to procure control devices from a limited number of vendors, and to account for the other complexities identified below.
- The process of redesigning a facility or installing additional controls will require some reduction in sterilization capacity. Moreover, the process of coming into compliance with the standards may require multiple facilities to reduce their sterilization capacity simultaneously. Based on comments received during the proposed rulemaking, the average reduction in capacity during the re-design and installation period can range from 10 percent [21] to 20 percent.[22] In addition, there is already strain on the medical device supply chain, and it is difficult for most facilities to absorb any additional demand for sterilized product. Three years is needed to ensure that owners and operators can come into compliance with the emissions standards while at the same time minimizing any potential impacts to the medical device supply chain, for which reliability is important to protect public health.
- There are a limited number of vendors that specialize in the redesign of facilities to be compliant with the PTE requirements of EPA Method 204. In addition, there are a limited number of control technology vendors that supply the types of advanced control systems that the EPA expects will be necessary for facilities to comply with the final standards. Three years is needed to ensure that all owners and operators can receive the necessary services and have the proper equipment in place by the compliance date.

For the same reasons explained above, existing sources will need more than the proposed 18 months to comply with the standards promulgated under CAA section 112(f)(2). As with standards promulgated under section 112(d)(2)–(3), 112(d)(5) and 112(d)(6), in most instances compliance with the section 112(f)(2) standards will require sources to plan, purchase, and install equipment for EtO control. For example, for SCVs at facilities where EtO use is at least 30 tpy, if an existing affected source currently does not achieve 99.99 percent control of EtO emissions and a new control system is needed to meet that limit, the facility will need time to properly engineer the project, obtain capital authorization and funding, procure the equipment, construct the equipment, start up the equipment, set up new software, develop operating procedures, and train operators on the new equipment. The additional factors identified above, such as avoiding impacts to medical device supply chains and securing control devices from a limited number of vendors, apply similarly to section 112(f)(2) standards as to standards promulgated under section 112(d)(2)–(3), 112(d)(5) and 112(d)(6).

If facilities commence work on these emissions reduction efforts immediately after this rule becomes effective, we believe that sources will be able to comply with the standards in this final rule within the two year compliance window set by § 112(f)(4), without substantial interruption in operations.

Specifically, we offer the following timeline as a general guide to completing the necessary upgrades in a timely manner:

- Step 1: Secure vendors for facility retrofits, control devices, EtO CEMS, and any other equipment and services that will be needed in order to comply with the NESHAP.
- Step 2: Work with vendors on (1) any new facility designs that will be required in order to meet the PTE requirements of EPA Method 204, (2) any new control system designs that will be required in order to meet the emission standards, (3) a schedule to ensure timely compliance with the NESHAP, and (4) purchase of the equipment that will be required in order to meet items (1) and (2), along with EtO CEMS.
- Step 3: Submit a permit application to the relevant permitting authority.
- Step 4: Complete the necessary facility retrofits, control device installations, and EtO CEMS installations.
- Step 5: Test the control systems and facility air handling systems in order to ensure that the NESHAP is being met.

We recognize that this is a significant undertaking for the industry, and we encourage facilities to engage in these

[21] Commenter provided the following statement: ''For example, a 10% reduction in capacity across the 83 commercial sterilizers in the U.S. implies that an additional 8 sterilization facilities will be required to maintain existing throughput'' (see Docket Item No. EPA–HQ–OAR–2019–0178–0618).

[22] Commenter provided the following statement: ''During . . . upgrades, EtO sterilization capacity was reduced by more than 20 percent as emissions control equipment was installed and tested.'' (see Docket Item No. EPA–HQ–OAR–2019–0178–0566).

steps as early as practicable, as opposed to delaying action until closer to the end of the compliance period.

Although we believe sources that follow this timeline will be able to comply with these standards within two years, to minimize any potential impact to the medical device supply chain, we are allowing up to three years for existing sources to comply with section 112(d)(2)–(3), 112(d)(5) and 112(d)(6) standards, the maximum timeframe authorized under CAA section 112(i)(3)(A). Further, CAA section 112(i)(3)(B) and EPA's regulation at 40 CFR 63.6(i)(4)(i)(A) authorize States with delegated authority to implement and enforce this NESHAP to grant an existing source an additional year to comply with section 112(d) standards, if such additional period is necessary for the installation of controls.[23] In addition, for each standard, owners and operators will have 180 days after the end of the relevant compliance period to begin demonstrating compliance with that standard. See 40 CFR 63.7(a)(2).

Lastly, if more time is needed to comply with any standard in this final rule, CAA section 112(i)(4) provides that ''The President may exempt any stationary source from compliance with any standard or limitation under this section for a period of not more than 2 years if the President determines that the technology to implement such standard is not available and that it is in the national security interests of the United States to do so. An exemption under this paragraph may be extended for 1 or more additional periods, each period not to exceed 2 years. The President shall report to Congress with respect to each exemption (or extension thereof) made under this paragraph.''

IV. What is the rationale for our final decisions and amendments for the Commercial Sterilization Facilities source category?

For each issue, this section provides a description of what we proposed and what we are finalizing for the issue, the EPA's rationale for the final decisions and amendments, and a summary of key comments and responses. For all comments not discussed in this preamble, comment summaries and the EPA's responses can be found in the comment summary and response document available in the docket.

[23] This flexibility has been available since the NESHAP was first promulgated (59 FR 62585, December 6, 1994) and continues to be available in the current NESHAP.

A. Amendments Addressing the Affected Source Definitions

1. What amendments did we propose to address the affected source definitions?

For SCVs, ARVs, and CEVs, we proposed to define the affected source as the individual vent. For Group 1 and Group 2 room air emissions we proposed to define the affected source as the collection of all room air emissions for each group at any sterilization facility. More information concerning the affected source definitions is in section III.A. of the proposal preamble (88 FR 22790, April 13, 2023).

2. How did the affected source definitions change since proposal?

We are finalizing the affected source definitions as proposed (88 FR 22790, April 13, 2023).

3. What key comments did we receive on the affected source definitions and what are our responses?

Comment: Two commenters suggested that the definition of an affected source should be based on control system outlets, stating that when emission streams are combined, the limit must be based on the actual achievable rate of control with further consideration for the modeled risk of the facility. One commenter suggested that the affected source should be defined as the sterilization facility as a whole, and another commenter stated the affected source definition(s) should consider destruction efficiency. Additionally, commenters expressed concerns that the affected source definitions for point sources (*i.e.,* SCVs, ARVs, and CEVs) would disproportionately favor facilities with smaller capacity and facilities with multiple individual vents regardless of size. Specifically, one commenter stated that a facility with multiple individual vents would have a higher ''emission rate ceiling'' with respect to mass rate (*i.e.,* lb/h) emission limits.

Response: We disagree with the commenters' suggestion that the definition of an affected source should be based on control system outlets or the sterilization facility as a whole. There are many different ways in which emission sources can be combined and controlled at commercial sterilization facilities. If affected source definitions were based on control system outlets, it is not clear which outlets (and, by extension, emission source combinations) would be selected and what the criteria for selecting those outlets would be. It is not feasible to set an emission standard for every conceivable combination of emission sources. Furthermore, the commenters do not provide any suggestions on which control system outlets should be considered when defining affected sources. The most straightforward approach is to define the affected source as the emission source itself and to have owners and operators decide how best to combine and control emissions from affected sources at their facilities. With respect to defining the affected source as the sterilization facility as a whole, there is very limited data available where a performance test has been conducted for an entire facility. Furthermore, defining the affected source as the sterilization facility would require a compliance mechanism that some facilities may find unnecessarily complicated, given that compliance demonstration has typically been conducted on a source-by-source basis. It is not clear and the commenter does not provide any explanation on how to base an affected source definition on destruction efficiency.

Lastly, regarding the comment that the definition of affected sources for point sources is disproportionally favorable to facilities with smaller capacity or with multiple individual vents, this is not an issue in the final rule. All of the emission standards in this final rule are in a percent reduction format, which is the same regardless of facility size or how many vents are in place. Therefore, concerns regarding ''emission rate ceilings'' are no longer relevant.

Comment: One commenter stated that there is unnecessary complexity to the proposed definitions of Group 1 and Group 2 room air emissions due to the variability in size and facility configuration, particularly as they apply to the proposed format of the emission standards for these sources (*i.e.,* lb/h). The commenter also stated that the definitions favor facilities which have smaller capacity and noted that individual facility characteristics must be considered for Group 1 and Group 2 emissions. Specifically, the commenter stated that emission rates should be based on technological feasibility to control emissions, including feasibility limitations regarding low inlet concentrations.

Response: We disagree with one commenter's assertion that there is unnecessary complexity to the proposed definitions of Group 1 and Group 2 room air emissions due to the variability in size and facility configuration. All sterilization facilities, regardless of size or configuration, follow the same basic procedure: sterilization and its associated activities (*e.g.,* EtO storage and dispensing, vacuum pump

operation, handling of pre-aeration sterilized product), aeration, and shipping. Group 1 room air emissions simply cover all activities that occur prior to aeration, and Group 2 room air emissions cover all activities that occur after aeration. Combining room air emissions based on whether they occur before or after aeration is a clear way to defining room air emissions affected sources. It also reflects the most common controlled room air configuration that we have observed. With respect to considering individual facility characteristics The simplest breakdown of controlled room air emissions that we have observed involves capturing and routing all emissions from post-aeration handling of sterilization material to one control system, and then capturing and routing all other room air emission sources (*i.e.,* Group 1 room air emissions) to another control system. It is important to define the affected sources for room air emissions in this manner so that owners and operators can have flexibility in how they chose to control their emissions,[24] and so that facilities who have already chosen to control their emissions in this manner can continue to do so while minimizing any potential compliance issues. With respect to the comment that the definition of affected sources for room air emissions is disproportionally favorable to facilities with smaller capacity, the comment appears to pertain more to the setting of the emission standards themselves, rather than the affected source definition. As discussed in section IV.B.3.b of this preamble, we are no longer finalizing mass rate emission standards, and we are accounting for technical feasibility (*e.g.,* manufacturer guarantees, emission reductions achieved in performance tests) when finalizing emission standards. The emission standards in this final rule for room air emissions are in a percent reduction format, which is the same regardless of facility size.

4. What is the rationale for our final approach and final decisions to address the affected source definitions?

We evaluated the comments on our proposed affected source definitions. For the reasons explained in the proposed rule (88 FR 22790, April 13, 2023), we determined that these amendments are necessary because the definition of an ''affected source'' at 40 CFR 63.2 is not appropriate for this source category. More information concerning the amendments we are finalizing for affected source definitions is in the preamble to the proposed rule and in the comments and our specific responses to the comments in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* available in the docket for this rulemaking. Therefore, we are finalizing the affected source definitions as proposed.

B. Amendments Pursuant to CAA Sections 112(d)(2), 112(d)(3), and 112(d)(5) for the Commercial Sterilization Facilities Source Category

1. What did we propose pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) for the Commercial Sterilization Facilities source category?

We proposed to establish standards under CAA sections 112(d)(2)–(3) and 112(d)(5) for the following emission sources that were unregulated: SCVs, ARVs, and CEVs at facilities where EtO use is less than 1 tpy, ARVs and CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, CEVs at facilities where EtO use is at least 10 tpy, and room air emissions. We also proposed a technical correction to the emission standard for ARVs at facilities where EtO use is at least 10 tpy. We proposed the following emission standards pursuant to CAA section 112(d)(2)–(3):

- 3.2E–4 lb/h for new and existing CEVs at facilities where EtO use is at least 10 tpy,
- 1.3E–3 lb/h for new and existing Group 1 room air emissions at major source facilities, and
- 2.8E–3 lb/h for new and existing Group 2 room air emissions at major source facilities.

For more information, see section III.B of the proposal preamble (88 FR 22790, April 13, 2023). We proposed the following emission standards pursuant to CAA section 112(d)(5):

- 99 percent emission reduction for new and existing SCVs at facilities where EtO use is less than 1 tpy,
- 99 percent emission reduction for new and existing ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy,
- 99 percent emission reduction for new and existing ARVs at facilities where EtO use is less than 1 tpy,
- 99 percent emission reduction for new and existing CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy,
- 99 percent emission reduction for new and existing CEVs at facilities where EtO use less than 1 tpy.
- 1.3E–3 lb/h emission limit for new and existing Group 1 room air emissions at area source facilities, and
- 2.8E–3 lb/h emission limit for new Group 2 room air emissions at area source facilities.

These are emissions standards that reflect the use of generally available control technologies. For more information, see section III.B of the proposal preamble (88 FR 22790, April 13, 2023).

For existing Group 2 room air emissions at area source facilities, pursuant to CAA section 112(d)(5), we proposed a requirement for facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017. This is a BMP that would reduce EtO use per sterilization cycle (*i.e.,* pollution prevention). For more information, see section III.B.8.g of the proposal preamble (88 FR 22790, April 13, 2023). In order to ensure complete capture of EtO emissions and, in turn, compliance with the proposed standards, we proposed to require each facility to operate areas with room air emissions subject to an emission standard in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51. For more information, see section III.B of the proposal preamble (88 FR 22790, April 13, 2023).

We addressed a necessary correction to the emission standards for these sources in 40 CFR 63.362(d) that allow facilities to either achieve 99 percent emission reduction or limit the outlet concentration to a maximum of 1 part per million by volume (ppmv), ''whichever is less stringent, from each aeration room vent.'' We proposed removing the less stringent 1 ppmv concentration alternative for these sources because it is not equivalent and therefore not an appropriate alternative to 99 percent emission reduction standard. For more information, see section III.B.2 of the proposal preamble (88 FR 22790, April 13, 2023).

2. How did the revisions pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) change since proposal for the Commercial Sterilization Facilities source category?

We are finalizing as proposed the following standards under CAA section 112(d)(5):

- 99 percent emission reduction for new and existing SCVs at facilities where EtO use is less than 1 tpy,
- 99 percent emission reduction for new and existing ARVs at facilities

[24] The EPA has not observed any instance where a facility is routing a portion of its Group 1 room air emissions to one control system, and the other portion to a different control system.

where EtO use is at least 1 tpy but less than 10 tpy, and

- 99 percent emission reduction for new and existing ARVs at facilities where EtO use is less than 1 tpy.

In addition, we are finalizing a requirement for each facility to operate areas with room air emissions subject to an emission standard in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51. We are also finalizing the removal of the 1 ppm alternative for ARVs at facilities where EtO use is at least 10 tpy, as proposed.

Based on comments received during the proposed rulemaking, we have revised the proposed standards for the following affected sources. The final emission standards pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) are as follows:

- 99.94 percent emission reduction for new and existing CEVs at major source facilities,
- 99 percent emission reduction for new and existing CEVs at area source facilities,
- 97 percent emission reduction for new and existing Group 1 room air emissions at major source facilities,
- 80 percent emission reduction for new and existing Group 1 room air emissions at area source facilities,
- 86 percent emission reduction for new and existing Group 2 room air emissions at major source facilities,
- For existing Group 2 room air emissions at area source facilities, lower the EtO concentration within each sterilization chamber to 1 ppm before the chamber can be opened, and
- 80 percent emission reduction for new Group 2 room air emissions at area source facilities.

For new and existing CEVs at major source facilities, as well as new and existing room air emissions at major source facilities, based on comments received during the proposed rulemaking, we have re-calculated the MACT floor based on percent emission reduction, as opposed to mass rate emissions. The primary reason for finalizing this change is that there is a serious concern that mass rate emission standards could result in operational reductions that could adversely impact the medical supply chain. The revised MACT floor for new and existing CEVs at major source facilities is 99.94 percent emission reduction. Because we were unable to identify more stringent (*i.e.,* beyond the floor or ''BTF'') options that are cost-effective, we are finalizing 99.94 percent emission reduction as the MACT standard under CAA section 112(d)(2)–(3) for new and existing CEVs at major source facilities. The revised MACT floor for new and existing Group 1 room air emissions at major source facilities is 90 percent emission reduction. We were able to identify a more stringent (*i.e.,* 97 percent control) and cost-effective BTF option and, therefore, we are finalizing a 97 percent emission reduction standard as the MACT standard under CAA section 112(d)(2)–(3) for new and existing Group 1 room air emissions at major source facilities. The revised MACT floor for new and existing Group 2 room air emissions at major source facilities is 86 percent emission reduction. Because the concentration that corresponds to this emission reduction is three times the representative detection level (RDL) for EtO, there are no BTF options to consider due to the potential difficulty of demonstrating compliance with limits lower than the MACT floor. Therefore, we are finalizing 86 percent emission reduction as the MACT standards for new and existing Group 2 room air emissions at major source facilities. For more information, see section IV.B.3.b of this preamble.

For both new and existing Group 1 room air emissions at area source facilities, as well as new Group 2 room air emissions at area source facilities, based on comments received during the proposed rulemaking, we are finalizing an 80 percent emission reduction standard, consistent with the manufacturer guarantee for the control technology on which the standard is based. The primary reason for the change from mass rate to percent reduction is that there is a serious concern that mass rate emission standards could result in operational reductions in order to meet the standards while still ensuring work health and safety, but that could adversely impact the medical supply chain. In addition, while some sources have demonstrated emission reductions higher than 80 percent, those reductions are limited to facilities with higher EtO usage rates, and we cannot determine whether smaller users of EtO can meet those emission reductions. For more information, see section IV.B.3.b of this preamble.

For existing Group 2 room air emissions at area source facilities, based on comments received during the proposed rulemaking, we are finalizing a revised BMP due to concerns that the BMP that we proposed (as well as alternatives for which we solicited comment in the proposal), would adversely impact the medical supply chain due to inefficiencies that would arise, as well as having to lengthen cycle dwell times in order to ensure sterility. The final requirement reduces existing Group 2 room air emissions at area source facilities by 20 percent, does not interfere with sterility assurance, and is expected to impact only 20 percent of facilities. We do not anticipate any severe negative impacts to the medical supply chain as a result of finalizing this requirement. For more information, see section IV.B.3.a of this preamble.

3. What key comments did we receive on the proposal revisions pursuant to CAA section 112(d)(2), 112(d)(3), and 112(d)(5), and what are our responses?

This section provides comment and responses for the key comments received regarding BMPs, mass rate emission standards, PTE, and warehouses. Other comment summaries and our responses for additional issues raised regarding these activities, as well as issues raised regarding our proposed emission standards for SCVs and ARVs at facilities where EtO use is less than 1 tpy, ARVs at facilities where EtO use is a least 1 tpy but less than 10 tpy, room air emissions at major source facilities, and our proposed technical correction to the emission standard for ARVs at facilities where EtO use is at least 10 tpy can be found in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* available in the docket for this rulemaking.

a. BMP

Comment: Several commenters contended that we should not require facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017. They stated that owners and operators should have the flexibility to optimize cycles using a variety of ISO/AAMI 11135 methods and that we should not limit or restrict the validation method that may be used.

One commenter stated that requiring facilities to follow the Cycle Calculation or Bioburden/Biological Indicator Approach would result in more dedicated product loads, more cycles needed to sterilize different project mixes, and most chambers not being filled to capacity. The commenter stated that de-consolidation of existing cycles to implement an appropriate Cycle Calculation or Bioburden/Biological Indicator approach would require (1) creation and validation of new product families, new process challenge devices, and biological indicators, (2) cycle development, and (3) maintenance through requalification and annual reporting. The commenter noted that the

extra burden associated with maintaining more cycles would create more work and require more chamber time, resulting in less sterilization capacity. Two commenters stated that requiring either the Cycle Calculation or Bioburden/Biological Indicator approach could limit research for product innovation as available development time in EtO sterilization chambers would be taken up for optimizing existing products.

Two commenters stated the ISO standards were intended for the process of EtO sterilization and not emission reduction or controls. One commenter further contended it is a faulty approach to base emission standards on international standards, as these standards are revised periodically and may continue to evolve. Another commenter noted that ISO/AAMI standards are currently being revised to be more flexible to achieve optimized cycles, while minimizing impact on sterilization capacity. The commenter contended that cycle validation must focus on achieving sterility required for patient safety and assuring product performance and reliability, and that reducing EtO use cannot take priority over patient safety.

One commenter stated that conducting Cycle Calculation studies for every product type or category would not be feasible with the current capacity. The commenter stated this would require effort to redesign sterilization cycles, evaluate product and packaging performance, and validate the redesigned cycles. The commenter also stated that the new validation work will impact sterilization capacity as sterilizer equipment is not available for production use during study times (*i.e.,* production capacity is diverted to cycle validation). The commenter further stated that sites that use more than one vendor would have to redesign sterilization cycles at each vendor and that, given the limited resources and expertise, this would not be possible to achieve on this scale. Another commenter stated they have not been able to ensure product sterility using Cycle Calculation approach.

Finally, one commenter stated that the Bioburden/Biological Indicator methods limit the number of products that can be validated in a single cycle. The commenter stated that the Bioburden/Biological Indicator approach may be limited to a range of products with similar attributes and drive up the number of required cycles. The commenter also stated that each validated cycle will require requalification every few years, and the additional testing at sterilizers and testing laboratories will decrease available sterilization capacity. The commenter stated that the inability to fill a sterilization chamber fully with product and waiting until full can lead to inefficient use of sterilization chambers and supply issues. Another commenter stated the Bioburden/Biological Indicator approach results in additional cost and delays, as it requires that the product bioburden levels be enumerated and characterized, and that consistency in the bioburden population and the bioburden's resistance to the sterilization process remain relatively stable over a multi-year period. The commenter also stated that it may take many years to establish the range in numbers and types of bioburden to properly perform a validation using this proposed Bioburden/Biological Indicator approach. Another commenter stated that the Bioburden approach would require upgrades to supplier facilities, manufacturing facility, and microbiological control practices.

Response: We agree with the commenters' concerns regarding potential inefficiencies in the sterilization process that may arise from requiring facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017, along with the potentially adverse impacts to the medical supply chain that could result from the proposed approach. These inefficiencies include reduced cycle optimization (*i.e.,* not being able to sterilize as much product per load or chamber), having to run more cycles overall in order to meet the demand for sterile medical devices, and diverting already strained resources away from normal operations to developing new cycle validations. We also agree with the commenters' concerns that requiring facilities to follow this requirement would limit research for product innovation. Given the current strain on resources, some companies may not be able to invest in additional chambers to conduct research. In addition, we agree with the commenters' concerns that because this requirement is based on international standards, which are revised periodically, this could result in potential future complications. Therefore, we are not including this requirement in the final rule.

Comment: As mentioned above, the EPA solicited comments on several other BMPs, including limiting EtO concentration limit and limiting packaging and pallet material. Two commenters stated that it is not technically feasible for facilities and products to meet a 290 milligrams per liter (mg/L) EtO concentration limit. One commenter stated that many industry guidelines and studies show that 400 mg/L is the minimum recommended concentration, and many products use higher concentrations to meet sterility assurance and product quality requirements as set forth by FDA. Another commenter stated that process efficiency is reduced with concentrations below 400 mg/L and that efficiency is constant at concentrations greater than 500 mg/L. One commenter indicated that an EtO concentration range of 400 to 650 mg/L is common practice because it achieves microbiological lethality for most products within a reasonable exposure time. Another commenter stated that product design, stability post-sterilization, and lethality are the drivers behind the choice of EtO concentration. The commenter also stated that research and development with biological indicators is routinely conducted using 600 mg/L cycles and that enforcing a lower limit may have an unintended negative consequence on the availability of biological indicators required for sterilization process validation and routine monitoring. One commenter stated we should not propose to limit the EtO concentration to 290 mg/L for small facilities and that we should, instead, allow performance-based standards. In addition, several commenters stated that an upper-bound limit on EtO concentration may lead to longer cycle times and dwell times and that longer dwell times would impact sterilization capacity and would lead to offshoring, as well as the construction of additional facilities.

One commenter stated limiting packaging and pallet material will interrupt trade, reduce innovation, increase the cost of medical devices, and disrupt the medical device manufacturing industry without a quantifiable reduction in EtO emissions. Two commenters stated that packaging and pallet material selection will drive the design of medical products. Two commenters noted that packaging requirements are in place to ensure a sterile barrier until use and to prevent product damage. One commenter stated packaging must pass rigorous test requirements, according to industry standards. Another commenter indicated that facilities use barcode instructions for use (IFUs) in place of paper IFUs when possible. However, paper IFUs are regulated by FDA. Two commenters noted that paper IFUs have not been documented to be a source of residual emissions. Another commenter

stated that there is no evidence that barcode materials would have less EtO retention than paper, and that labeling decisions have practical and legal considerations. One commenter noted that a minimal amount of plastic wrap is used to ensure the structural integrity of pallets during shipping and that excessive plastic is not in the interest of sterilization facilities, as it slows EtO penetration. The commenter also stated that kits are transported in cardboard to protect from punctures, and it is not possible to eliminate cardboard. A puncture to a kit means the kit needs to be re-sterilized, requiring use of additional EtO. One commenter stated that changes to pallet material could have supply chain issues given interoperability and weight requirements. Finally, another commenter stated that pallet materials impact the strength and design of pallet, and any issues would have implications for the entre medical device supply chain.

Response: We agree with the commenters' concerns regarding the issues with prescribing an upper-bound limit on in-chamber EtO concentration, as well as the negative impacts to the medical supply chain that could result from increasing the dwell time to maintain sterility as an outcome of such a requirement. Therefore, we are not including this requirement in the final rule. We also agree with the commenters' concerns regarding the need to ensure a sterile barrier through sufficient packaging, as well as the potential supply chain impacts from placing limits on the types of pallets that may be used. Therefore, we are not requiring limits on packaging or transport materials as part of this rulemaking.

Comment: One commenter recommended an end of sterilization cycle chamber limit of less than 1 ppm (with a zero mg/L reading) in the sterilization chamber (EtO remaining calculated measurement) as a BMP. The commenter stated that removing EtO from the sterilization chamber is the most efficient stage for EtO removal. The commenter further stated that longer EtO dwell times, as well as the potential for the elimination of nitrogen gas washes to keep total cycle time equivalent, could result in more EtO residual at aeration and the greater potential for room air emissions after aeration.

Response: We agree with the commenter's suggestion of a requirement to limit the in-chamber EtO concentration to 1 ppm. It does not interfere with sterility assurance, and, based on responses to the December 2019 questionnaire and September 2021 Information Collection Request (ICR), 80 percent of all commercial sterilization facilities, regardless of annual EtO use, are already meeting this limit. Those who are not meeting the limit currently are close to the limit,[25] so we do not anticipate any severe negative impacts to the medical device supply chain as a result of finalizing this requirement. We estimate that the emission reductions from applying this requirement to the source category would be 20 percent. In addition, since 80 percent of facilities are already meeting this limit, this would result in an 80 percent reduction in costs. We have evaluated the changes in cost, emissions, and cost-effectiveness for this BMP, and it is more cost-effective than the other options we considered. Therefore, for Group 2 room air emissions we are finalizing the BMP such that the in-chamber EtO concentration is to be lowered to 1 ppm before the chamber can be opened. We note that, even though this BMP is expected to result in fewer emission reductions than the BMP we proposed, this rule will still reduce EtO emissions (and, therefore, lifetime cancer risks) in multiple communities across the country. As discussed in section IV.C.2.a.iii, this BMP will ultimately apply only to facilities where EtO use is less than 4 tpy. We are finalizing the requirement that area source facilities whose EtO usage is at least 4 tpy but less than 20 tpy and area source facilities whose EtO usage is at least 20 tpy are required to reduce Group 2 room air emissions by 80 percent and 98 percent, respectively (see section IV.C.2.a.iii for more information). For SCVs and ARVs at facilities where EtO use is less than 1 tpy, as well as ARVs at facilities where EtO use is less than 10 tpy, our general rationale for proposing emission standards over the BMP was that emission standards would both achieve greater emission reduction and incur fewer annual costs than the BMP. However, even considering lower annual costs for the BMP, the emission standards would still achieve greater emission reduction. Therefore, for SCVs and ARVs at facilities where EtO use is less than 1 tpy, as well as ARVs at facilities where EtO use is less than 10 tpy, we are finalizing the emission standards as proposed pursuant to CAA section 112(d)(5). For CEVs at area source facilities, as well as room air emissions at area source facilities, we are also evaluating percent emission reduction standards, as opposed to mass rate emission standards. The revised GACT analyses for those emission sources are presented in section IV.B.3.b of this preamble.

Comment: Several commenters stated that we do not have the legislative authority or expertise to regulate sterilization cycles and that FDA is the Federal agency that has authority to regulate medical device sterilization. They stated that Congress gave FDA the authority to ensure the availability of safe and effective medical products and that we must not finalize any regulatory requirements that are under FDA purview.

Response: The EPA proposed the BMP (*i.e.,* require facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach) pursuant to CAA section 112(d)(5), which authorizes the EPA to set standards for area sources that provide for the use of generally available control technologies or management practices to reduce emissions. In addition, CAA section 112(h)(1) authorizes the EPA to promulgate a design, equipment, work practice or operational standard, or a combination thereof, if the EPA does not think it can prescribe an emission standard. We have identified modification of the post-sterilization process (*e.g.,* reducing the EtO concentration within the sterilization chamber prior to opening the chamber) as a BMP that can reduce EtO emissions from certain affected sources at commercial sterilization area source facilities. Neither CAA section 112(d)(5) nor section 112(h)(1) limits the scope of management or work practices that the EPA may consider in setting standards to control HAP, nor did the commenter identify any such legal limitation in the CAA or other applicable legal authorities. As discussed above, we are not finalizing the proposed BMP; in response to comment, we are finalizing a requirement for area source facilities with existing Group 2 room air emissions to lower the in-chamber EtO concentration to 1 ppm before the chamber is opened.[26] As discussed in

[25] The highest concentration that was reported prior to opening the chamber door was 20 ppm. While this may seem high, this is reduced from starting EtO concentrations of several thousand ppm (see section IV.F.3 of this preamble for further discussion).

[26] We have previously regulated the in-chamber EtO concentration when we established standards for CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy (59 FR 62586, December 6, 1994). These requirements were removed initially due to safety concerns regarding the regulation of emissions from CEVs, not related to any limitations on our authority. See discussion in section III.B.5 of the proposal preamble (88 FR 22790, April 13, 2023) for more information regarding why safety is

Continued

section IV.C.2.a.iii of this preamble, this requirement will ultimately apply only to existing Group 2 room air emissions at facilities where EtO use is less than 4 tpy. Based on responses to the December 2019 questionnaire and the September 2021 ICR, we have not identified any facilities where EtO use is less than 4 tpy that are not currently meeting this requirement. Therefore, in general, we do not anticipate that any facilities will need to go through a new cycle validation as a result of this requirement. Based on our conversations with FDA, this requirement is not anticipated to have an adverse impact on the medical device supply chain.

b. Mass Rate Emission Standards

Comment: Several commenters were opposed to mass rate emission standards, stating that they do not account for the substantial variability among volumetric flow rates in sterilization operations. The commenters expressed concerns with potential operational reductions needed in order to meet the standards while still ensuring worker health and safety, as well as compliance with EPA Method 204. The commenters suggested that we finalize emission reduction and outlet concentration standards instead. In addition, these commenters recommended that these standards be based on control device manufacturer guarantees. One commenter stated that, based on their discussions with control device manufacturers, they believe that the best and most advanced technologies will be guaranteed to meet a 99 percent emission reduction standard for CEVs and an 80 percent emission reduction standard for room air emissions.

Response: We agree with the commenters' concerns regarding the potential impacts of mass rate emission standards. Given the low outlet EtO concentration of these streams, along with current EtO detection levels, a mass rate emission standard essentially functions as an upper-bound limit on volumetric flow rate. It may not be appropriate to limit volumetric flow rate in this fashion, as additional flow may be needed in order to demonstrate compliance with EPA Method 204 or to ensure worker health and safety. If volumetric flow rate is limited, a facility may be forced to reduce its sterilization capacity in order to meet the mass rate emission standards. However, we disagree with the commenters' suggestion that outlet concentration standards be considered. We are concerned that some owners and operators may choose to dilute the air flow of the emissions stream rather than control emissions, in order to meet an outlet concentration standard, which would not result in emission reductions. In order to ensure emission reductions from an outlet concentration standard, an upper-bound limit on the volumetric flow rate would be necessary. As we have discussed before, this may be inappropriate for the source category. Therefore, although we proposed mass emission rate standards, we are finalizing percentage emission reduction standards in their place, and those specific standards are discussed later in this section.

We re-calculated the MACT floor for existing CEVs at major source facilities. We ranked the percent reduction performance of the CEVs ''for which the EPA has emissions information'' and found the best performing 12 percent of CEVs consists of one CEV that is being controlled by a gas/solid reactor.[27] Because the variability and uncertainty associated using available, short-term data would tend to reduce the minimum percent reduction, we then used the lower, not upper, prediction limit approach to develop the MACT floor for existing sources.[28] The LPL approach predicts the level of emissions that the sources upon which the floor is based are expected to meet over time, considering both the average emissions level achieved as well as emissions variability and the uncertainty that exists in the determination of emissions variability given the available, short-term data. For LPLs, our practice is to use the first percentile, or LPL 1, as that is the level of emission reductions that we are 99 percent confident is achieved by the average source represented in a dataset over a long-term period based on its previous, measured performance history as reflected in short term stack test data. The LPL 1 value of the existing source MACT floor is 99.94 percent emission reduction. The LPL 1 EtO concentration that corresponds to this emission reduction rate is 49 ppbv. Based on our review of available EtO measurement instruments and our demonstration program, we find the in-stack detection level for EtO, given the current technology, and potential makeup of emission streams, is approximately 10 ppbv. Some EtO CEMS manufacturers claim instrument detection levels much lower than 10 ppbv. However, we believe at the current time, 10 ppbv is the lowest level that can be consistently demonstrated and replicated across a wide range of emission profiles. We expect that EtO CEMS manufacturers, measurement companies, and laboratories will continue to improve EtO detection levels (making them lower). In the meantime, consistent with our practice regarding reducing relative measurement imprecision by applying a multiplication factor of three to the RDL, the average detection level of the best performers, or, in this case, the better performing instruments, so that measurements at or above this level have a measurement accuracy within 10 to 20 percent—similar to that contained in the American Society of Mechanical Engineers (ASME) ReMAP study,[29] we apply a multiplication factor of three to the RDL of 10 ppbv, which yields a workable-in-practice lower measurable value of 30 ppbv. For reference, below is the equation that relates the percent emission reduction, inlet EtO concentration, and outlet EtO concentration:

$$ER = \frac{EtO_{IM} - EtO_{OM}}{EtO_{IM}}$$

Where, *ER* is the percent emission reduction, EtO_{IM} is the inlet EtO mass, and EtO_{OM} is the outlet EtO mass. Since

not a concern regarding the requirements finalized in this action.

[27] See CAA section 112(d)(3). See also, *National Ass'n of Clean Water Agencies* v. *EPA,* 734 F.3d 1115, 1131 (2013) (citing *Sierra Club* v. *EPA,* 167 F.3d 658, 661 and 662) (''We accorded *Chevron* deference to EPA's . . . estimate of the MACT floor, noting that the requirement that the existing unit floors 'not be less stringent than the average emissions limitation achieved by the best performing 12 percent of units' does not, on its own, dictate 'how the performance of the best units is to be calculated, . . . [and] recognizing that 'EPA typically has wide latitude in determining the extent of data gathering necessary to solve a problem.' '')

[28] The variability for a DRE format limit requires use of a lower prediction limit (LPL), the UPL template was therefore modified for use to determine the LPL; rather than use of the 99th percentile that captures the ''right tail'' of the data distribution, the LPL template uses the 1st percentile, *i.e.,* captures the ''left tail'' of the data distribution (the t-statistic is 0.01). The LPL differs from the more commonly used UPL in that variability and uncertainty associated with percent reduction limits tend to make the predicted limits smaller than their averages; for UPL applications, variability and uncertainty associated with emission limits tend to make those predicted limits larger than their averages. Both approaches—UPL and LPL—rely on the same set of equations developed for the UPL; they only differ in the selected percentile. In other words, the LPL relies on calculations associated with the first percentile (LPL 1) of the data distribution, which is below the fiftieth percentile (LPL 50), or average for data with a normal distribution, while the UPL relies on calculations associated with the ninety-ninth percentile (UPL 99) of the data distribution, which is above the fiftieth percentile (UPL 50), or average for data with a normal distribution. Also note that for data in a normal distribution, LPL 50 = UPL 50.

[29] See the discussion in the MATS rule preamble at 77 FR 9370, February 16, 2012.

the outlet EtO concentration that corresponds to the MACT floor of 99.94 percent emission reduction is above 3×RDL, there are more stringent (*i.e.,* BTF) options to consider.[30] We considered two BTF options for reducing EtO emissions from this source: the first option is 99.95 percent emission reduction, and the second option reflects the most stringent emission reduction for which compliance can be demonstrated. With respect to the second option, the most stringent emission reduction for which compliance can be demonstrated is that which corresponds to an outlet concentration of 30 ppbv (*i.e.,* 3xRDL). This emission reduction is 99.96 percent, which is lower than all of the reported emission reductions in the test runs that were used to calculate the MACT floor. The impacts of these options are presented in table 7. Because we have not identified any major source facilities with existing CEVs, the impacts are based on a model plant for existing CEVs at a synthetic area source facility with the following assumptions reflecting the average of each of the parameters at synthetic area source facilities:

- Annual EtO use: 200 tpy.
- Annual operating hours: 8,000.
- Portion of EtO going to CEVs: 1 percent.
- CEV flow rate: 278 cubic feet per second (cfs).

TABLE 7—NATIONWIDE EMISSIONS REDUCTION AND COST IMPACTS OF BTF OPTIONS CONSIDERED UNDER CAA SECTIONS 112(d)(2) AND 112(d)(3) FOR CEVS AT MAJOR SOURCE FACILITIES

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
MACT Floor ..	99.94 percent emission reduction	$830,000	$176,000	2.4E–2 [480 lb/yr]	$735,000 [$370/lb].
1	99.95 percent emission reduction	184,000	65,500	2.0E–4 [0.4 lb/year]	328,000,000 [$164,000/lb].
2	99.96 percent emission reduction	184,000	66,200	2.0E–4 [0.4 lb/year]	331,000,000 [$166,000/lb].

While we acknowledge that EtO is a highly toxic HAP, the cost estimates above are far outside the range of the cost-effectiveness values that we have determined to be cost-effective for highly toxic HAPs (*e.g.,* we finalized a requirement with a cost-effectiveness of $15,000/lb ($30,000,000/ton) for existing small hard chromium electroplating to provide an ample margin of safety (taking into account cost among other factors) (77 FR 58227–8, 58239). Based on the estimates above, we find neither option to be cost effective. Therefore, the final MACT standard for existing CEVs at major source facilities is 99.94 percent emission reduction.

For new sources, CAA section 112(d)(3) requires that the standard shall not be less stringent than the emission control that is achieved in practice by the best controlled similar source. In this case, the best controlled similar source is also the CEV that is being controlled by a gas/solid reactor and the data of which is used to determine the MACT floor for existing sources. Therefore, the new source MACT floor is equivalent to the existing source MACT floor, which is 99.94 percent emission reduction. As explained above, because this emission reduction limit is above the lowest level at which compliance can be demonstrated, the EPA considered more stringent (*i.e.,* BTF) options. We considered the same BTF options as those evaluated for existing CEVs at major source facilities, for the same reasons explained above. The first BTF option would require achieving 99.95 percent emission reduction, and the second BTF option would require achieving 99.96 percent emission reduction. The impacts of these options are presented in table 7 of this preamble. Because we have not identified any major source facilities with existing CEVs, the impacts are based on a model plant for existing CEVs at a synthetic area source facility. Based on the estimates above and for the reason explained above, we find neither option to be cost effective. Therefore, the final MACT standard for new CEVs at major source facilities is 99.94 percent emission reduction. For the reasons explained above, our final MACT standards under CAA sections 112(d)(2) and (3) for both new and existing CEVs at major source facilities require these facilities to reduce the EtO emissions from new and existing CEVs by 99.94 percent.

For existing CEVs at area source facilities, we considered two potential GACT options for reducing EtO emissions from this group: the first option reflects the use of emission controls on the CEVs, and the second option reflects applying a BMP to lower the in-chamber EtO concentration to 1 ppm before the chamber is opened (*i.e.,* pollution prevention). With respect to the first option, because 34 out of 40 area source facilities with CEVs already using controls to reduce CEV emissions, and we have no reason to believe that the other six cannot do the same, we consider emission controls to be generally available for existing CEVs at these facilities. Evaluating the available information on controls, including the documented control efficiency for 12 facilities in the category, we determined that a control efficiency of 99 percent is generally available for existing CEVs at area source facilities. The second potential GACT option we considered was the same management practice discussed in section IV.B.3.a of this preamble, which would require facilities to lower the in-chamber EtO concentration to 1 ppm before the chamber is opened. The impacts of these two options are presented in table 8.

[30] As Judge Williams explained in his concurring opinion in *Sierra Club* v. *EPA,* CAA ''Section 112(d)(2) calls for emissions standards that are the most stringent that the EPA finds to be 'achievable,' taking into account a variety of factors including cost. . . . The ''achievable'' standards have come to be known as the ''beyond-the-floor'' standards, . . . meaning, obviously, ones more stringent than the ''floors'' established under § 112(d)(3).'' 479 F.3d 875, 884 (D.C. Cir. 2007).

TABLE 8—NATIONWIDE EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR EXISTING CEVS AT AREA SOURCE FACILITIES

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99 percent emission reduction	$1,750,000	$740,000	3.84 [7,680 lb/year]	193,000 [$96/lb]
2	BMP (estimated 20 percent emission reduction)	0	$3,560,000 (one-time annual cost) [1].	0.796 [1,590 lb/year]	$4,470,000 [$2,240/lb]

[1] This includes the cost for testing to verify that the new sterilization process will lower the in-chamber EtO concentration to 1 ppm before the chamber is opened, as well as preparing and submitting the necessary paperwork to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, and considering EtO is a highly potent carcinogen, the cost-effectiveness numbers of these options are within the range of the values that we have determined to be cost-effective for highly toxic HAPs. Such values include hexavalent chromium, where we finalized a requirement with a cost-effectiveness of $15,000/lb ($30,000,000/ton) for existing small hard chromium electroplating to provide an ample margin of safety (taking into account cost among other factors) (77 FR 58227–8, 58239). We are finalizing Option 1 for the following reasons. First, while both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve much greater emission reduction than Option 2. Second, Option 1 would incur fewer annual costs than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are finalizing Option 1 for existing CEVs at area source facilities. Specifically, we are finalizing a requirement for these facilities to continuously reduce emissions from existing CEVs by 99 percent.

For new CEVs at area source facilities, we considered two potential GACT options similar to those evaluated for existing CEVs at area source facilities. The first potential GACT option would require achieving 99 percent emission reduction. The second potential GACT option we considered is a BMP described in section IV.B.3.a, which would require facilities to lower the in-chamber EtO concentration to 1 ppm before the chamber is opened. The impacts of these options, which are presented in table 9 of this preamble, are based on a model plant for new CEVs at a new area source facility with the following assumptions reflecting the average of each of the parameters at existing area source facilities:

- Annual EtO use: 100 tpy.
- Annual operating hours: 8,000.
- Portion of EtO going to CEVs: 1 percent.
- CEV flow rate: 200 cubic feet per second (cfs).
- Number of unique cycles: nine.

TABLE 9—NATIONWIDE EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR NEW CEVS AT AREA SOURCE FACILITIES

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99 percent emission reduction	$553,000	$142,000	0.99 [1,980 lb/year]	$144,000 [$72/lb]
2	BMP (estimated 20 percent emission reduction)	0	$80,000 (one-time annual cost) [1].	0.20 [400 lb/year]	$400,000 [$200/lb]

[1] This includes the cost for testing to verify that the new sterilization process will lower the in-chamber EtO concentration to 1 ppm before the chamber is opened, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, and considering EtO is a highly potent carcinogen, the cost-effectiveness number of Option 2 is within the range of the values that we have determined to be cost-effective for highly toxic HAPs. While both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve greater emission reductions than Option 2, and it is more cost-effective. Therefore, we are finalizing Option 1 as the standard for new CEVs at area source facilities under CAA section 112(d)(5). The standard requires these facilities to continuously reduce emissions from new CEVs by 99 percent.

We have re-calculated the MACT floor for existing Group 1 room air emissions at major source facilities. We ranked the performance of the facilities with Group 1 room air emissions for which data are available based on percent emission reduction. There are only three performance tests that are currently available, only one of which contains three test runs. Therefore, the best performing 12 percent of facilities for which data are available consists of one facility with three test runs that is controlling its Group 1 room air emissions with a gas/solid reactor. That facility reported an emission reduction of 98 percent. We then used the LPL approach, as mentioned previously, to develop the MACT floor for existing sources. The LPL 1 value of the existing source MACT floor is 90 percent emission reduction. The outlet EtO concentration (UPL 99 value) that corresponds to this emission reduction is 93 ppbv. Since this is above 3×RDL, there are more stringent (*i.e.,* BTF) options to consider. We considered two BTF options for reducing EtO emissions from this source: the first option we considered was 95 percent emission reduction. The first option reflects the lowest emission reduction that we have observed in performance tests, and The second option reflects the most stringent emission reduction for which compliance can be demonstrated. With respect to the second option, the most stringent emission reduction for which compliance can be demonstrated is that which corresponds to an outlet concentration of 30 ppbv (*i.e.,* 3xRDL). This emission reduction is 97 percent, which is lower than two of the three reported values in the test runs that were used to calculate the MACT floor. The impacts of these options are presented in table 10 (along with the MACT floor impacts). Because we have

not identified any major source facilities with existing Group 1 room air emissions, the impacts are based on a model plant for existing Group 1 room air emissions at a synthetic area source facility with the following assumptions reflecting the average of each of the parameters at synthetic area source facilities:

- Annual EtO use: 140 tpy.
- Annual operating hours: 8,000.
- Portion of EtO going to Group 1 RAE: 0.4 percent.
- Group 1 room air emission flow rate: 400 cubic feet per second (cfs).

TABLE 10—NATIONWIDE EMISSIONS REDUCTION AND COST IMPACTS OF BTF OPTIONS CONSIDERED UNDER CAA SECTIONS 112(d)(2) AND 112(d)(3) FOR GROUP 1 ROOM AIR EMISSIONS AT MAJOR SOURCE FACILITIES

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
MACT floor	90 percent emission reduction	$830,000	$176,000	0.168 [336 lb/year]	$1,050,000 [$525/lb].
1	95 percent emission reduction	553,000	129,000	2.80E–2 [56.0 lb/year]	$4,610,000 [$2,300/lb].
2	97 percent emission reduction	461,000	113,000	1.12E–2 [22.4 lb/year]	$10,100,000 [$5,040/lb].

Based on the estimates above, and considering EtO is a highly potent carcinogen, the cost-effectiveness numbers are within the range of the values that we have determined to be cost-effective for highly toxic HAPs. While both options are considered BTF under CAA sections 112(d)(2), Option 2 would achieve greater emission reductions than Option 1. Therefore, the final MACT standard under CAA sections 112(d)(2) and (3) for existing Group 1 room air emissions at major source facilities is 97 percent emission reduction.

For new sources, CAA section 112(d)(3) requires that the standard shall not be less stringent than the emission control that is achieved in practice by the best controlled similar source. In this case, the best controlled similar source is also the Group 1 room air emissions that are being controlled by a gas/solid reactor and the data of which is used to determine the MACT floor for existing sources. Therefore, the new source MACT floor is equivalent to the existing source MACT floor, which is 90 percent emission reduction. We considered the same BTF options as those evaluated for existing Group 1 room air emissions at major source facilities for the same reasons explained above. The first BTF option would require achieving 95 percent emission reduction, and the second BTF option would require achieving 97 percent emission reduction. The impacts of these options are presented in table 10 of this preamble. Because we have not identified any major source facilities with existing Group 1 room air emissions, the impacts are based on a model plant for new Group 1 room air emissions at a synthetic area source facility. Based on the estimates above, and considering EtO is a highly potent carcinogen, the cost-effectiveness numbers are within the range of the values that we have determined to be cost-effective for highly toxic HAPs. While both options are considered BTF under CAA sections 112(d)(2), Option 2 would achieve greater emission reductions than Option 1. Therefore, the final standard for new Group 2 room air emissions at major source facilities is 97 percent emission reduction. We also considered non-air quality health and environmental impacts and energy requirements when evaluating the BTF options. Further discussion of these considerations is presented in the document *MACT Floor Analysis for Ethylene Oxide Commercial Sterilization—Chamber Exhaust Vents and Room Air Emission Sources—Promulgation Rule Review for the Ethylene Oxide Commercial Sterilization Source Category,* available in the docket for this rulemaking.

For existing Group 1 room air emissions at area source facilities, we considered two potential GACT options for reducing EtO emissions from this group: the first option reflects the use of emission controls on Group 1 room air emissions, and the second option is the same BMP discussed above (lowering the in-chamber EtO concentration to 1 ppm before the chamber is opened). With respect to the first option, 32 out of 74 area source facilities with Group 1 room air emissions are already using controls to reduce those emissions.[31] We considered a standard of 80 percent emission reduction, which is the manufacturer guarantee for room air emissions controls provided by one of the commenters. We find this standard to be reasonable for existing Group 1 room air emissions at area source facilities because it is the manufacturer guarantee, which means that it is a level of emission reduction that all sources can achieve. While some sources have demonstrated emission reductions higher than 80 percent, those reductions are limited to facilities with higher EtO usage rates, and we cannot determine whether smaller users of EtO can meet those emission reductions. The second potential GACT option we considered was the same management practice discussed in section IV.B.3.a, which would require facilities to lower the in-chamber EtO concentration to 1 ppm before the chamber is opened. During the sterilization process, EtO becomes trapped within the material and continues to off-gas after the sterilization process is complete. Therefore, if more EtO is driven out of the product prior to opening the chamber, this can lead to a reduction in post-sterilization EtO emissions, including those from pre-aeration handling of sterilized material. The impacts of these options are presented in table 11.

[31] The Group 1 room air emission reduction at these facilities ranges from 52 percent to 99.8 percent. It should be noted that the facility with the emission reduction at the upper bound of this range uses 135 tpy of EtO.

TABLE 11—NATIONWIDE EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR EXISTING GROUP 1 ROOM AIR EMISSIONS AT AREA SOURCE FACILITIES

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	80 percent emission reduction	$91,000,000	$12,900,000	3.66 [7,320 lb/year] ..	$3,530,000 [$1,770/lb].
2	BMP (estimated 20 percent emission reduction).	$0	$5,040,000 (one-time annual cost) [1].	1.13 [2,260 lb/year] ..	$4,460,000 [$2,230/lb].

[1] This includes the cost for testing to verify that the new sterilization process will lower the in-chamber EtO concentration to 1 ppm before the chamber is opened, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, and considering EtO is a highly potent carcinogen, the cost-effectiveness numbers of these options are within the range of the values that we have determined to be cost effective for highly toxic HAPs. We are finalizing Option 1 because while both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve greater emission reduction than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are finalizing Option 1 for existing Group 1 room air emissions at area source facilities. Specifically, we are finalizing a requirement for these facilities to continuously reduce emissions from existing Group 1 room air emissions by 80 percent.

For new Group 1 room air emissions at area source facilities, we considered the same two potential GACT options as those evaluated for existing Group 1 room air emissions at area source facilities for the same reasons explained above. The first potential GACT option (Option 1) would require achieving an emission reduction of 80 percent. The second potential GACT option we considered (Option 2) is a BMP that would require facilities to lower the in-chamber EtO concentration to 1 ppm before the chamber is opened. The impacts of these options, which are presented in table 12 of this preamble, are based on a model plant for new Group 1 room air emissions at an area source facility with the assumptions reflecting the average of each of the parameters at area source facilities with new Group 1 room air emissions as described in section III.B.8.c of the proposal preamble.

TABLE 12—MODEL PLANT EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR NEW GROUP 1 ROOM AIR EMISSIONS AT AREA SOURCE FACILITIES

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	80 percent emission reduction	$922,000	$192,000	0.288 [576 lb/year] ...	$666,000 [$333/lb].
2	BMP ..... (estimated 20 percent emission reduction)	0	$80,000 (one-time annual cost) [1].	7.20E–2 [144 lb/year]	$1,110,000 [$556/lb].

[1] This includes the cost for testing to verify that the new sterilization process will lower the in-chamber EtO concentration to 1 ppm before the chamber is opened, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, we find both options to be cost effective. While both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve greater emission reductions than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are finalizing standards for new Group 1 room air emissions at area source facilities. Specifically, we are finalizing a requirement for these facilities to continuously reduce emissions from new Group 1 room air emissions by 80 percent.

We re-calculated the MACT floor for existing Group 2 room air emissions at major source facilities. We ranked the performance of the facilities with Group 2 room air emissions for which data are available based on percent emission reduction. There are only three performance tests that are currently available, only one of which contains three test runs. Therefore, the best performing 12 percent of facilities for which data are available consists of one facility with three test runs that is controlling its Group 2 room air emissions with a gas/solid reactor. That facility reported an emission reduction of 96 percent. As mentioned previously, we then used the LPL approach to develop the MACT floor for existing sources. The LPL 1 value of the existing source MACT floor is 94 percent emission reduction. The outlet EtO concentration (LPL 1 value) that corresponds to this emission reduction is 10 ppbv. Since this is below 3×RDL, we adjusted the MACT floor by determining the emission reduction using 30 ppbv and the LPL 1 value of the inlet EtO concentration of the Group 2 room air emissions stream at the facility, which is 0.12 ppmv. This results in an adjusted MACT floor of 86 percent emission reduction. Since this represents 3×RDL, there are no more stringent (*i.e.,* BTF) options to consider, as there would be difficulty demonstrating compliance at any such lower limit. Therefore, the final MACT standard under CAA sections 112(d)(2) and (3) for existing Group 2 room air emissions at major source facilities is 86 percent emission reduction.

For new sources, CAA section 112(d)(3) requires that the standard shall not be less stringent than the emission control that is achieved in practice by the best controlled similar source. In this case, the best controlled similar source is also the Group 2 room air emissions that are being controlled by a gas/solid reactor and the data of which is used to determine the MACT

floor for existing sources. Therefore, the new source MACT floor is equivalent to the existing source MACT floor, which is 86 percent emission reduction. As explained above, because this emission limit represents the lowest level at which compliance can be demonstrated, the EPA did not consider more stringent (*i.e.,* BTF) options. Therefore, the proposed standard for new Group 2 room air emissions at major source facilities is 86 percent emission reduction.

For existing Group 2 room air emissions at area source facilities, we considered two potential GACT options for reducing EtO emissions from this group: the first option reflects the use of emission controls on Group 2 room air emissions, and the second option is the same BMP discussed above (lowering the in-chamber EtO concentration to 1 ppm before the chamber is opened). With respect to the first option, 30 out of 80 area source facilities with Group 2 room air emissions are already using controls to reduce those emissions.[32] We considered a standard of 80 percent emission reduction, which is the manufacturer guarantee for room air emissions controls provided by one of the commenters. We find this standard to be reasonable for existing Group 2 room air emissions at area source facilities because it is the manufacturer guarantee, which means that it is a level of emission reduction that all sources can achieve. While some sources have demonstrated emission reductions higher than 80 percent, those reductions are limited to facilities with higher EtO usage rates, and we cannot determine whether smaller users of EtO can meet those emission reductions. The second potential GACT option we considered was the same management practice discussed in section IV.B.3.a, which would require facilities to lower the in-chamber EtO concentration to 1 ppm before the chamber is opened. During the sterilization process, EtO becomes trapped within the material and continues to off-gas after the sterilization process is complete. Therefore, if more EtO is driven out of the product prior to opening the chamber, this can lead to a reduction in post-sterilization EtO emissions, including those from post-aeration handling of sterilized material. The impacts of these options are presented in table 13.

TABLE 13—NATIONWIDE EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR EXISTING GROUP 2 ROOM AIR EMISSIONS AT AREA SOURCE FACILITIES

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	80 percent emission reduction	$236,000,000	$32,700,000	1.10 [2,200 lb/year]	$29,700,000 [$14,900/lb].
2	BMP (estimated 20 percent emission reduction).	0	$5,440,000 (one-time annual cost) [1].	0.311 [622 lb/year]	$17,500,000 [$8,750/lb].

[1] This includes the cost for testing to verify that the new sterilization process will lower the in-chamber EtO concentration to 1 ppm before the chamber is opened, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, and considering EtO is a highly potent carcinogen, the cost-effectiveness numbers of these options are within the range of the values that we have determined to be cost-effective for highly toxic HAPs. Further, as discussed in section III.B.8.g of the proposal preamble (88 FR 28790, April 13, 2023), there are multiple factors we consider in assessing the cost of the emission reductions. See *NRDC* v. *EPA,* 749 F.3d 1055, 1060 (D.C. Cir. April 18, 2014) (''Section 112 does not command the EPA to use a particular form of cost analysis.''). These factors include, but are not limited to, total capital costs, total annual costs, cost-effectiveness, and annual costs compared to total revenue (*i.e.,* costs to sales ratios). Our established methodology for assessing economic impacts of regulations indicates that the potential for adverse economic impacts begins when the cost to sales ratio exceeds three percent. According to our estimates, the annual cost of the emission control option for most of the affected sources discussed above is well below three percent.[33] However, reducing existing Group 2 room air emissions at area source facilities using emission control devices (Option 1), would significantly impact several companies operating a total of nine area source facilities with Group 2 room air emissions. We estimate that the annual cost of controls at the level under Option 1 would exceed three percent of revenue for these companies.[34] Based on the available economic information, assuming market conditions remain approximately the same, we are concerned that these companies would not be able to sustain the costs associated with Option 1. In addition, according to FDA, six of these facilities could impact the availability of the medical devices described in section I.A.1 of this preamble. Therefore, pursuant to CAA section 112(d)(5), we are finalizing Option 2 as the GACT standard for existing Group 2 room air emissions at area source facilities. Specifically, this GACT standard requires facilities to lower the in-chamber EtO concentration to 1 ppm before the chamber is opened.[35]

For new Group 2 room air emissions at area sources facilities, we considered the same two potential GACT options as those evaluated for existing Group 1 room air emissions at area source facilities for the same reasons explained above. The first potential GACT option (Option 1) would require achieving an emission reduction of 80 percent. The second potential GACT option we considered (Option 2) is a BMP that would require facilities to lower the in-chamber EtO concentration to 1 ppm before the chamber is opened. The impacts of these options, which are presented in table 14 of this preamble, are based on a model plant for new Group 2 room air emissions at an area source facility with the assumptions reflecting the average of each of the parameters at area source facilities with

[32] The Group 2 room air emission reduction at these facilities ranges from 30 percent to 99.97 percent. It should be noted that the facility with the emission reduction at the upper bound of this range uses 135 tpy of EtO.

[33] See memorandum, *Technical Support Document for Proposed Rule—Industry Profile, Review of Unregulated Emissions, CAA Section 112(d)(6) Technology Review, and CAA Section 112(f) Risk Assessment for the Ethylene Oxide Emissions Standards for Sterilization Facilities NESHAP,* located at Docket ID No. EPA–HQ–OAR–2019–0178.

[34] The issue of high cost-to-sales ratios is present only for this option and, thus, is not discussed for other options.

[35] As discussed in section IV.C.2.a.iii of this preamble, this GACT standard will ultimately apply only to facilities where EtO use is less than 4 tpy. Facilities where EtO use is at least 4 tpy will be required to meet an emission standard established under CAA section 112(f)(2).

new Group 1 room air emissions as described in section III.B.8.h of the proposal preamble.

TABLE 14—MODEL PLANT EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR NEW GROUP 2 ROOM AIR EMISSIONS AT AREA SOURCE FACILITIES

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	80 percent emission reduction	$1,840,000	$332,000	3.6E–2 [72 lb/year]	$9,170,000 [$4,560/lb].
2	BMP (estimated 20 percent emission reduction).	0	$40,000 (one-time annual cost)[1].	9.1E–3 [18 lb/year]	$4,375,000 [$2,190/lb].

[1] This includes the cost for testing to verify that the new sterilization process will lower the in-chamber EtO concentration to 1 ppm before the chamber is opened, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, and considering EtO is a highly potent carcinogen, the cost-effectiveness numbers of these options are within the range of the values that we have determined to be cost-effective for highly toxic HAPs. As discussed earlier in this section, this includes hexavalent chromium, where we finalized a requirement with a cost-effectiveness of $15,000/lb ($30,000,000/ton) for existing small hard chromium electroplating to provide an ample margin of safety (taking into account cost among other factors) (77 FR 58227–8, 58239). Although both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve four times the emission reductions of Option 2. Therefore, pursuant to CAA section 112(d)(5), we are finalizing standards for new Group 2 room air emissions at area source facilities. Specifically, we are finalizing a requirement for these facilities to continuously reduce emissions from new Group 2 room air emissions by 80 percent.

c. PTE

Comment: We received extensive comment on our proposal to require that each facility must operate areas with room air emissions subject to an emission standard under the PTE requirements of EPA Method 204. Some commenters were supportive of this requirement, stating that other regulatory bodies have already required this and that this is the correct protocol for ensuring that emissions are captured and routed to a control system. Other commenters were opposed to this requirement, stating that EPA Method 204 was established for smaller point source operations (*e.g.,* paint booths, spray coating), as opposed to larger sterilization facilities. Several commenters cited other technical concerns, including the fact that not every facility is currently configured to meet the PTE requirements of EPA Method 204. The commenters suggested broad alternatives, including a simple requirement to operate areas with room air emissions subject to an emission standard under negative pressure.

Response: We strongly disagree with the commenters that EPA Method 204 is not appropriate to apply to this source category. The design requirements of EPA Method 204 are agnostic to the industry it is applied. It has been applied widely to any industrial processes that needs to control VOC emissions, including several existing commercial sterilizers that have already been complying with EPA Method 204. In order to meet the emission standards, it is necessary to ensure that all emissions are captured and routed to a control system. Our established protocol in numerous new source performance standards, NESHAPs, and federally enforceable State and local programs (*e.g.,* title V permits, State implementation plans) for ensuring complete capture of room air emissions is EPA Method 204. We recognize that many commercial sterilizers will need to retrofit their facilities to meet the PTE requirements of EPA Method 204, similar to facilities that have already done so. We have accounted for the cost to retrofit facilities by scaling the cost from a large facility that conducted a retrofit. Furthermore, based on our knowledge regarding the application of EPA Method 204 in general, retrofitting to meet this method can be complicated, depending on the size of the facility. However, commercial sterilization facilities tend to be simple buildings (in some cases, re-purposed warehouses) with a relatively small footprint, which helps the retrofitting process. The emission standards for room air emissions that we evaluated assume 100 percent capture of EtO emissions,[36] and the costs of complying with the PTE requirements of EPA Method 204 were included in our BTF and GACT evaluations. We found each emission standard that we evaluated to be cost-effective (see section IV.B.3.b of this preamble for more information). In addition, the term ''negative pressure'' is vague and can imply any capture efficiency between zero and 100 percent. The commenters did not provide specific suggestions for alternative capture efficiencies, nor did they provide the criteria that would be used to demonstrate that those efficiencies are being met, and we are unable to evaluate alternative negative pressure requirements as a result. Therefore, EPA Method 204 is appropriate to apply to this source category in order to ensure complete capture of room air emissions.

Comment: Several commenters requested various flexibilities and clarifications with respect to the PTE requirements of EPA Method 204. Several commenters expressed concern with Criterion 5.1 of EPA Method 204, stating that it would not be possible to always ensure that doors are ''at least four equivalent opening diameters'' from all EtO storage media or post-aeration sterilized product, particularly during loading and unloading operations. Two commenters recommended that we revise the standards to permit implementation of cascading air systems to capture room air emissions.[37] One commenter stated that these systems would provide greater flexibility to accommodate sterilization operations that could not implement a PTE, would offer EtO capture and control efficiency that was as effective as a PTE, and would have fewer manufacturing implications and potential adverse impacts. Finally, two

[36] Section 2 of EPA Method 204 states, in part, ''If the criteria are met and if all the exhaust gases from the enclosure are ducted to a control device, then the volatile organic compounds (VOC) capture efficiency (CE) is assumed to be 100 percent, and CE need not be measured.''

[37] These are systems that move air from ambient pressure, through warehouse ventilation, secondary aeration, primary aeration, the sterilizer chamber, and ultimately to an air pollution control device to capture and control EtO emissions. This is opposed to other systems where air from one source is captured and then directly sent to a control system.

commenters expressed concern with Criteria 5.2, 5.3, and 5.5 of EPA Method 204.

Response: Criterion 5.1 of EPA Method 204 states that ''Any natural draft opening (NDO) shall be at least four equivalent opening diameters from each VOC emitting point unless otherwise specified by the Administrator.'' [38] We disagree with the commenters' concerns that Criterion 5.1 of EPA Method 204 will not be possible to meet for doors where either EtO storage media is moved into a PTE or post-aeration sterilized material is moved out of a PTE. There may be certain facility designs where such an exemption is either necessary or unnecessary in order to ensure complete capture of room air emissions. However, the EPA does not have enough information to make that determination for all facilities within the source category as part of this rulemaking. Criterion 5.1 of EPA Method 204 allows delegated authorities to exempt any NDO from this requirement, as needed. Therefore, we are not exempting Criterion 5.1 of EPA Method 204 for doors where either EtO storage media is moved into a PTE or post-aeration sterilized material is moved out of a PTE as part of this final rule. Instead, we are relying on the delegated authorities to make that determination for their commercial sterilization facilities, as provided in Criterion 5.1., as they are in a better place to determine whether there are sufficient measures in place to capture any emission points within four equivalent opening diameters of an NDO. With respect to cascading air systems, we disagree with the commenters' suggestion that they be permitted in place of the PTE requirements of EPA Method 204, as they are insufficient on their own to ensure complete capture of room air emissions. However, it is not our intent to discourage or prohibit the use of these systems altogether. Cascading air systems may be used to capture and route room air emissions to a control device. However, in order to ensure complete capture of room air emissions, if such a system contains one or more areas that are subject to the PTE requirements of EPA Method 204, then the entire system must be treated as a single enclosure that is subject to those requirements.

For all other flexibilities suggested by the commenters, we provide the following responses:

- Criterion 5.2 of EPA Method 204 states that ''Any exhaust point from the enclosure shall be at least four equivalent duct or hood diameters from each NDO.'' One commenter stated that Criterion 5.2 may not be possible for all facilities due to preexisting layouts. This criterion only applies to temporary total enclosures, as opposed to PTEs, and is not required in the final rule.
- Criterion 5.3 of EPA Method 204 states that ''The total area of all NDO's shall not exceed 5 percent of the surface area of the enclosure's four walls, floor, and ceiling.'' One commenter stated that the presence of garage doors could exceed the requirement that NDOs not exceed five percent of the PTE total floor space. However, we note that facilities can be, and have been, re-designed in order to meet the PTE requirements of EPA Method 204, including Criterion 5.3. Therefore, we are not finalizing any exceptions for this criterion.
- Criterion 5.5 of EPA Method 204 states that ''All access doors and windows whose areas are not included in section 5.3 and are not included in the calculation in section 5.4 shall be closed during routine operation of the process''. Two commenters expressed concern with Criterion 5.4 of EPA Method 204. However, the commenters did not provide any explanation as to why exceptions for Criterion 5.5 of EPA Method 204 should be made. Therefore, we are not finalizing any exceptions for this criterion.

d. Warehouses

Comment: We received extensive comments on the regulation of warehouses, particularly stand-alone (*i.e.,* off-site) warehouses. Most commenters were supportive of regulating emissions from all warehouses, stating that sterilized materials can continue to off-gas significant quantities of EtO after being moved to a warehouse. Several commenters pointed to a stand-alone warehouse in Georgia, where the State estimated that potential pre-control EtO emissions were approximately 5,000 lb/year. One commenter was opposed to including standards for stand-alone warehouses as part of this final rule, stating that we could, instead, identify potentially applicable facilities, collect data from these facilities, and then determine if further regulation is necessary.

Response: It is our understanding that there are three types of warehouses within this industry: attached warehouses, co-located warehouses, and stand-alone warehouses. Attached warehouses are those that are part of an EtO sterilization building. Co-located warehouses are those that are detached from but ''contiguous'' (including adjacent) to and ''under common control'' with the EtO sterilization building, including leased properties.[39] Stand-alone warehouses are those that are not attached to or co-located with an EtO sterilization building. According to our record at the time of category listing, ''the Commercial Sterilization Facilities source category includes ''*facilities which use ethylene oxide* in any equipment which destroys bacteria, viruses, fungi, insects, or other unwanted microorganisms or materials when such facilities are engaged in the growth, manufacture, construction, transportation, retail or wholesale trade, or storage of commercial products, or when such facilities are engaged in the operation of museums, art galleries, arboreta, or botanical or zoological gardens or exhibits. Not included in this category are hospitals, doctor offices, veterinary offices, clinics, and other facilities where medical services are rendered'' (emphasis added).[40] Under this definition, warehouses that are part of facilities which use EtO, including attached and co-located warehouses, are part of the source category and, therefore, subject to the standards for Group 2 room air emissions. However, because stand-alone warehouses do not use EtO, they are not included in the source category definition. Furthermore, we do not have sufficient information to understand where these warehouses are located, who owns them, how they are operated, or what level of emissions potential they may have. While several commenters note that emissions information is available for at least one stand-alone warehouse, it is unknown whether the emissions information for this facility is representative of all stand-alone warehouses. Thus, standards for these facilities are not included as part of this final rule. However, as suggested by one commenter, we are planning to gather information from stand-alone warehouses as soon as possible to

[38] Per 40 CFR 51.100(s), EtO is a VOC.

[39] This final rule establishes standards under CAA section 112 for both major and area sources of commercial sterilization facilities. As the EPA explained in its final rule promulgating the General Provisions for NESHAP pursuant to section 112, ''[f]or the purposes of implementing section 112, the major/area source determination is made on a plant-wide basis; that is, HAP emissions from all sources located within a contiguous area and under common control are considered in the determination.'' 59 FR 12408, 12411 (March 16, 1994). The EPA noted that ''the common dictionary term ''contiguous'' consists, in part, of ''nearby, neighboring, adjacent,'' and that ''the EPA has historically interpreted 'contiguous property' to mean the same as 'contiguous or adjacent property' in the development of numerous regulations to implement the Act.'' *Id.* at 12412.

[40] *Documentation for Developing the Initial Source Category List, Final Report,* page A–83 (see EPA–450/3–91–030, July 1992).

understand what the source category looks like and its emission potential and, if necessary, develop a regulatory action that both lists a new source category and proposes standards for stand-alone warehouses handling EtO sterilized medical devices. This information gathering effort may include engaging with State and local agencies and non-governmental organizations, as well as conducting an ICR(s) pursuant to CAA section 114.

The remaining comments and our specific responses can be found in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* available in the docket for this rulemaking.

4. What is the rationale for our final approach and final decisions for the revisions pursuant to CAA section 112(d)(2), 112(d)(3), and 112(d)(5)?

We evaluated the comments on our proposed standards for SCVs, ARVs, and CEVs at facilities where EtO use is less than 1 tpy, ARVs and CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, CEVs at facilities where EtO use is at least 10 tpy, and room air emissions, as well as our proposed technical correction to the emission standard for ARVs at facilities where EtO use is at least 10 tpy. As explained above in section IV.B.3 and in Chapter 4 of the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* we made changes in the final rule based on comments received during the proposed rulemaking. More information and rationale concerning all the amendments we are finalizing pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) is in the preamble to the proposed rule (88 FR 22790, April 13, 2023), in section IV.B.3 of this preamble, and in the comments and our specific responses to the comments in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* which is available in the docket for this rulemaking. Therefore, we are finalizing the proposed standards for SCVs and ARVs at facilities where EtO use is less than 1 tpy, finalizing the proposed standards for ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, finalizing standards for CEVs, finalizing the proposed emission standards for room air emissions at major sources facilities, finalizing emission standards for room air emissions at area source facilities, and finalizing the proposed revisions for ARVs at facilities where EtO use is at least 10 tpy.

C. Residual Risk Review for the Commercial Sterilization Facilities Source Category

1. What did we propose pursuant to CAA section 112(f) for the Commercial Sterilization Facilities source category?

Pursuant to CAA section 112(f), we conducted a residual risk review and presented the results of this review, along with our proposed decisions regarding risk acceptability and ample margin of safety, in the April 13, 2023, proposed rule for 40 CFR part 63, subpart O (88 FR 22790). The results of the risk assessment for the proposal are presented briefly in table 15 of this preamble. As discussed in section III.A of the proposed rule, all baseline risk results were developed using the best estimates of actual emissions, and we did not conduct a separate assessment of allowables at proposal. More detail is in the residual risk technical support document, *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2023 Risk and Technology Review Proposed Rule,* which is available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2019–0178–0482).

TABLE 15—COMMERCIAL STERILIZATION FACILITIES SOURCE CATEGORY BASELINE RISK ASSESSMENT RESULTS IN THE PROPOSAL

Number of facilities [1]	Maximum individual cancer risk (in 1 million) [2]	Estimated population at increased risk of cancer		Estimated annual cancer incidence (cases per year)	Maximum chronic noncancer TOSHI	Maximum screening acute noncancer hazard quotient (HQ)
		>100-in-1 million	≥1-in-1 million			
97 [3]	6,000	18,000	8,300,000	0.9	0.04	0.002 (REL).

[1] Number of facilities evaluated in the risk analysis.

[2] Maximum individual excess lifetime cancer risk due to HAP emissions from the source category.

[3] As part of the risk assessment for the proposed rulemaking, there were 86 facilities in the Commercial Sterilization Facilities source category in operation and 11 research and development facilities, for a total of 97 facilities. To exercise caution with respect to this source category, we included research facilities in our assessment because there was a lack of certainty over whether these were true research facilities, for which CAA section 112(c)(7) requires that a separate category be established. However, EtO use at these facilities tends to be very low (less than 1 tpy), and these facilities had low risk.

The results of the proposed chronic baseline inhalation cancer risk assessment at proposal indicated that, based on estimates of current actual emissions, the MIR posed by the source category was 6,000-in-1 million. At proposal, the total estimated cancer incidence from this source category was estimated to be 0.9 excess cancer cases per year, or one case in every 1.1 years. Approximately 8.3 million people were estimated to have cancer risks at or above 1-in-1 million from HAP emitted from the facilities in this source category. At proposal, the estimated maximum chronic noncancer target organ-specific hazard index (TOSHI) for the source category was 0.04, indicating low likelihood of adverse noncancer effects from long-term inhalation exposures.

As shown in table 15 of this preamble, the acute risk screening assessment of reasonable worst-case inhalation impacts indicates a maximum acute HQ of 0.002 for propylene oxide based on the reference exposure level (REL) acute health reference value.[41] For EtO, the maximum HQ is 0.0005 based on the acute exposure guideline level (AEGL)–2 acute health reference value.[42]

At proposal, the maximum lifetime individual cancer risk posed by the 97 modeled facilities, based on whole facility emissions, was 6,000-in-1 million, with EtO emissions from SCVs and Group 2 room air emissions from the Commercial Sterilization Facilities source category driving the risk. Regarding the noncancer risk

[41] Not to be confused with the ''recommended exposure limit'', which is used by the National Institute for Occupational Safety and Health.

[42] Acute RELs, ERPG–1, and AEGL–1 acute health reference values are not available for ethylene oxide.

assessment, the maximum chronic noncancer TOSHI posed by whole facility emissions was estimated to be 0.04 (for the neurological system as the target organ), driven by emissions of EtO from source category sources.

We weighed all health risk factors, including those shown in table 15 of this preamble, in our risk acceptability determination and proposed that the risks posed by this source category under the current provisions are unacceptable. At proposal, we identified several options to control EtO emissions from SCVs and Group 2 room air emissions.

To reduce risks, we considered two additional control options after implementation of controls under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5). Control Option 1 would have required a 99.94 percent emission reduction standard for SCVs at facilities where EtO use is at least 40 tpy, as well as a 2.8 E–3 lb/h standard for existing Group 2 room air emissions at area source facilities where EtO use is at least 20 tpy. We determined that this would have resulted in a source category MIR of 400-in-1 million. Control Option 2 would have imposed the same requirements as Control Option 1, but it would also have required facilities where the MIR is greater than 100-in-1 million after Control Option 1 is imposed to limit their existing Group 2 room air emissions to a maximum volumetric flow rate of 2,900 dscfm and a maximum EtO concentration of 30 ppbv. This would have resulted in a source category MIR of 100-in-1 million. We proposed Control Option 2 and solicited comment on Control Option 1.

We proposed that, after implementation of the proposed controls for SCVs and Group 2 room air emissions at commercial sterilization facilities, the resulting risks would be acceptable for this source category. In our proposal, we presented the risk impacts using health risk measures and information, including the MIR, cancer incidence, and associated uncertainty in emissions estimates after application of the proposed options to control EtO emissions from Group 2 room air emissions (88 FR 22790, April 13, 2023). At proposal, we determined application of the controls for SCVs and Group 2 room air emissions would reduce the estimated MIR from 6,000-in-1 million to 100-in-1 million.

We then considered whether the standards provide an ample margin of safety to protect public health and whether, taking into consideration costs, energy, safety, and other relevant factors, additional standards are required to prevent an adverse environmental effect. To determine whether the rule provides an ample margin of safety, we considered the requirements that we proposed to achieve acceptable risks. In addition, we considered more stringent controls for SCVs, as well as expanding the emission standard and work practice standards for existing Group 2 room air emissions to all facilities in the source category. In considering whether the standards should be tightened to provide an ample margin of safety to protect public health, we considered the same risk factors that we considered for our acceptability determination and also examined the costs, technological feasibility, and other relevant factors related to emissions control options that might reduce risk associated with emissions from the source category. Based on these considerations, we proposed that the standards that we proposed to achieve acceptable risks, along with a 99.94 percent emission reduction standard for SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy and a 99.8 percent emission reduction standard for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, would provide an ample margin of safety to protect public health (section III.D.2 of the proposal preamble, 88 FR 22790, April 13, 2023). We also solicited comment on which of the available control options should be applied in order to provide an ample margin of safety to protect public health.

2. How did the risk review change for the Commercial Sterilization Facilities source category?

a. Commercial Sterilization Facilities Source Category Risk Assessment and Determination of Risk Acceptability (Step 1)

As part of the final risk assessment, the EPA reanalyzed risks to include allowable emissions (which we did not include at the proposal stage), changes since proposal to certain emission standards being finalized for previously unregulated sources, and three additional facilities identified by commenters. Allowable emissions are the maximum amount that facilities are allowed to emit under CAA section 112(d) standards. For previously unregulated sources, since there were no CAA section 112(d) standards in place, the allowable emissions in the baseline risk assessment are equal to the uncontrolled emissions from these sources. In some instances, the actual emissions for these sources are lower than the allowable emissions. This is because some facilities are already controlling these sources as a result of local requirements or through voluntary control measures.[43] The revised emissions used to reanalyze risks are available in the docket for this rulemaking (see section IV.C.3 of this preamble and Appendix 1 of the *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2024 Risk and Technology Review Final Rule*).

Based on the actual emission estimates, the results of the chronic inhalation cancer risk from the risk assessment indicate that the maximum lifetime individual cancer risk posed by the 88 facilities could be as high as 6,000-in-1 million, with EtO as the major contributor to the risk. The total estimated cancer incidence from the revised risk assessment is 0.9 excess cancer cases per year, or one excess case in every 1.1 years. Of the approximately 115 million people that live within 50 kilometers (km) of the 88 facilities included in the risk assessment, 8.5 million people were estimated to have cancer risks greater than or equal to 1-in-1 million from HAP emitted from the facilities in this source category, and approximately 19,000 are estimated to have cancer risks greater than 100-in-1 million (table 16 of this preamble).

The estimated maximum chronic noncancer TOSHI for the source category remained unchanged from the proposal at 0.04, indicating low likelihood of adverse noncancer effects from long-term inhalation exposures. Additionally, the worst-case acute HQ remained unchanged from proposal (0.002 for propylene oxide based on the REL acute health reference value).

The maximum lifetime individual cancer risk based on whole facility emissions was 6,000-in-1 million driven by EtO emissions from the Commercial Sterilization Facilities source category. The maximum chronic noncancer TOSHI posed by whole facility emissions was estimated to be 0.04 (for the neurological system as the target organ), driven by emissions of EtO from source category sources.

[43] As discussed later in this section, for previously unregulated sources, the allowable emissions in the risk assessment that considers controls we are promulgating under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) are equal to the controlled emissions from these sources assuming that they are only controlled to the degree that we are requiring pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5). In some instances, the actual emissions for these sources may still be lower than the allowable emissions. This is because some facilities are already controlling these sources to a degree greater than what we are finalizing pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) as a result of local requirements or through voluntary control measures.

Based on allowable emission estimates, the maximum lifetime individual cancer risk could be as high as 8,000-in-1 million, with EtO driving the risk. The total estimated cancer incidence is 8 excess cancer cases per year, or 1 excess case in every 1.5 months. Approximately 62 million people were estimated to have cancer risks greater than or equal to 1-in-1 million from allowable emissions, and approximately 260,000 are estimated to have cancer risks greater than 100-in-1 million (table 16 of this preamble).

TABLE 16—COMMERCIAL STERILIZATION FACILITIES SOURCE CATEGORY BASELINE RISK ASSESSMENT RESULTS BASED ON REVISED EMISSIONS IN FINAL RULE

Number of facilities [1]	Maximum individual cancer risk (in 1 million) [2]	Estimated population at increased risk of cancer		Estimated annual cancer incidence (cases per year)	Maximum chronic noncancer TOSHI	Maximum screening acute noncancer HQ
		>100-in-1 million	≥1-in-1 million			
Actual Emissions						
88 [3]	6,000	19,000	8,500,000	0.9	0.04	0.002 (REL).
Allowable Emissions						
88 [3]	8,000	260,000	62,000,000	8	0.05	

[1] Number of facilities evaluated in the risk analysis.
[2] Maximum individual excess lifetime cancer risk due to HAP emissions from the source category.
[3] Two of the 90 facilities identified in the source category are planned or under construction and therefore were not included in the risk assessment.

Risks were then estimated after application of the controls finalized in this rulemaking pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5). A summary of those controls is presented in table 17.

TABLE 17—SUMMARY OF STANDARDS AFTER TAKING ACTIONS PURSUANT TO CAA SECTIONS 112(d)(2), 112(d)(3), AND 112(d)(5)

Emission source	Existing or new?	EtO use	Standards	CAA section
SCV	Existing and new.	At least 10 tpy	99 percent emission reduction	Current standard.
		At least 1 but less than 10 tpy	99 percent emission reduction	Current standard.
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
ARV	Existing and new.	At least 10 tpy	99 percent emission reduction	Current standard.
		At least 1 but less than 10 tpy	99 percent emission reduction	112(d)(5).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
CEV at major sources	Existing and new.	N/A	99.94 percent emission reduction [1]	112(d)(2) and 112(d)(3).
CEV at area sources	Existing and new.	N/A	99 percent emission reduction [1]	112(d)(5).
Group 1 room air emissions at major sources.	Existing and new.	N/A	97 percent emission reduction [1 2]	112(d)(2) and 112(d)(3).
Group 1 room air emissions at area sources.	Existing and new.	N/A	80 percent emission reduction [1 2]	112(d)(5).
Group 2 room air emissions at major sources.	Existing and new.	N/A	86 percent emission reduction [1 2]	112(d)(2) and 112(d)(3).
Group 2 room air emissions at area sources.	Existing	N/A	Lower the EtO concentration within each sterilization chamber to 1 ppm before the chamber can be opened.[1]	112(d)(5).
	New	N/A	80 percent emission reduction [1 2]	112(d)(5).

[1] This standard is different from what was proposed.
[2] To assure compliance with the emission limit, we are requiring each facility to operate areas with these emissions in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51.

Based on the risk assessment considering controls finalized under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5), the maximum lifetime individual cancer risk could be as high as 6,000-in-1 million, with EtO driving the risk. For previously unregulated sources, the allowable emissions in this risk assessment are equal to the controlled emissions from these sources assuming that they are only controlled to the degree that we are requiring pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5). In some instances, the actual emissions for these sources may still be lower than the allowable emissions. This is because some facilities are already controlling these sources to a degree greater than what we are finalizing pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) as a result of local requirements or through voluntary control measures. The total estimated

cancer incidence could be as high as 4 excess cancer cases per year, or 1 excess case in every 3 months. As many as 38 million people are estimated to have cancer risks greater than or equal to 1-in-1 million, and approximately 85,000 people are estimated to have cancer risks greater than 100-in-1 million (table 18 of this preamble).

However, as noted above, some facilities are currently performing better than the controls finalized under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5), and in that case we estimate the maximum lifetime individual cancer risk as 5,000-in-1 million, with EtO driving the risk. The total estimated cancer incidence is estimated to be 0.4 excess cancer cases per year, or 1 excess case in every 2.5 years. Approximately 4.2 million people were estimated to have cancer risks greater than or equal to 1-in-1 million, and approximately 3,900 are estimated to have cancer risks greater than 100-in-1 million (table 18 of this preamble), based only on the application of the CAA section 112(d)(2), 112(d)(3), and 112(d)(5) actions being finalized.

TABLE 18—COMMERCIAL STERILIZATION FACILITIES SOURCE CATEGORY RISK ASSESSMENT RESULTS BASED ON EMISSIONS AFTER CONTROLS PROMULGATED UNDER CAA SECTIONS 112(d)(2)–(3) AND 112(d)(5)

Number of facilities [1]	Maximum individual cancer risk (in 1 million) [2]	Estimated population at increased risk of cancer [2]		Estimated annual cancer incidence (cases per year) [2]
		>100-in-1 million	≥1-in-1 million	
88 [3]	[4] 5,000–6,000	[4] 3,900–260,000	[4] 4,200,000–62,000,000	[4] 0.4–4

[1] Number of facilities evaluated in the risk analysis.
[2] Maximum individual excess lifetime cancer risk due to HAP emissions from the source category.
[3] Two of the 90 facilities identified in the source category are planned or under construction and therefore were not included in the risk assessment.
[4] Ranges in values account for if all facilities were performing at the level of the standards (high end) to considering facilities that are currently performing better than the standards (low end).

Based on the revised risk assessment results considering controls finalized under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5), we continue to find that the risks are unacceptable, as we did during the proposal due to emissions of EtO from SCVs, ARVs, Group 1 room air emission, Group 2 room air emissions, and CEVs. Pursuant to CAA section 112(f)(2), the EPA must first determine the emission standards necessary to reduce risks to an acceptable level, and then determine whether further HAP emissions reductions are necessary to provide an ample margin of safety to protect public health or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. Immediately below is a discussion of the standards the EPA has evaluated for bringing risks to an acceptable level (step 1).

i. SCV Emissions

There are 26 facilities within the source category where the ''revised allowable emissions'' from SCVs (*i.e.,* allowable emissions after implementing existing and newly promulgated 112(d) standards in this final rule) contribute to the facilities' MIRs exceeding 100-in-1 million, and EtO usage at these facilities ranges from four tpy to 446 tpy. The previous subpart O required 99 percent emission reduction for SCVs at facilities where EtO use is at least 1 tpy. An emission reduction of 99 percent is also the final standard under CAA section 112(d)(5) for the previously unregulated SCVs, which were those at facilities where EtO use is less than 1 tpy (see section IV.B.2).

Our data do not identify any add-on controls beyond those we have already considered when promulgating or reviewing the SCV standards in the previous subpart O or finalizing the standards for the previously unregulated SCVs in section IV.B. However, our evaluation of the performance test data and manufacturer guarantees shows that these controls can achieve greater than 99 percent reduction. We therefore considered more stringent SCV standards for facilities where EtO use is at least 1 tpy, which would include all 26 facilities where the revised allowable emissions from SCVs contribute to the facilities' MIRs exceeding 100-in-1 million.

We evaluated 99.8 percent reduction of SCV emissions from facilities using at least 1 tpy but less than 10 tpy of EtO.[44] As discussed in section III.D.2 of the proposal preamble (88 FR 22790, April 13, 2023), 99.8 percent is the maximum emission reduction from SCV with which compliance can be demonstrated at all facilities with EtO usage within this range.[45] A 99.8 percent reduction would eliminate SCV emissions as a contributor to a facility's MIR exceeding 100-in-1 million for facilities using at least 1 tpy but less than 10 tpy of EtO.[46] We have determined that a 99.8 percent emission reduction standard is feasible because of one commenter's statement that, based on their discussions with control device manufacturers, the best and most advanced technologies will be guaranteed to meet a 99.9 percent emission reduction standard for SCVs.

For facilities using at least 10 tpy, further reduction would be needed to eliminate SCV emissions as a contributor to a facility's MIR exceeding 100-in-a-million. We evaluated 99.9 percent reduction, which as mentioned above reflects the manufacturer guaranteed control level. A 99.9 percent reduction would eliminate SCV emissions as a contributor to facilities' MIRs exceeding 100-in-1 million for facilities using at least 10 tpy but less than 30 tpy of EtO. As discussed in section III.D.2 of the proposal preamble (88 FR 22790, April 13, 2023), we evaluated a 99.94 percent emission reduction standard for these facilities as part of Control Option A under the second step of the residual risk review. However, as discussed in section IV.C.3 of this preamble, several commenters stated that we do not have representative performance tests for SCVs. While this is not true for the whole source category, it is true for facilities where EtO use is at least 10 tpy but less than 30 tpy. Therefore, as part of this final rule, we did not evaluate an

[44] The MIRs of facilities with EtO usage less than 1 tpy are all below 100-in-a-million.

[45] *i.e.,* Based on facility characteristics, there is no compliance demonstration issue because the required EtO concentration to meet this limit would be at or above 30 ppbv (which is 3 × RDL).

[46] A facility with usage amount in this range may still have a MIR exceeding 100-in-a-million due to other emissions.

emission reduction standard more stringent than the manufacturer guarantee for SCVs at these facilities.

For facilities using at least 30 tpy, further reduction would be needed to eliminate SCV emissions as a contributor to a facility's MIR exceeding 100-in-1 million. We evaluated 99.99 percent reduction based on a performance test showing this level of reduction from a facility within this group. A 99.99 percent reduction would eliminate SCV emissions as a contributor to a facility's MIR exceeding 100-in-a-million for facilities using at least 30 tpy of EtO. We received comment on the technical feasibility of emission standards that exceed the manufacturer guarantee for SCVs (*i.e.,* 99.9 percent emission reduction), but we do not have any information suggesting that any facility within this group cannot achieve 99.99 percent emission reduction. See section IV.C.3 of this preamble for more information.

ii. ARV Emissions

There are three facilities where revised allowable ARV emissions contribute to the facility's MIR exceeding 100-in-1 million, and EtO use at these facilities currently ranges from 44 tpy to 446 tpy of EtO. The previous subpart O required a 1 ppm maximum outlet concentration or 99 percent emission reduction for ARVs at facilities where EtO use is at least 10 tpy. As discussed in section IV.B, we are removing the 1 ppm maximum outlet concentration alternative standard, and we are finalizing 99 percent emission reduction standards under CAA section 112(d)(5) for previously unregulated ARVs, which were those at facilities where EtO use is less than 10 tpy. As a result, the final 112(d) standard for ARV emissions at all facilities is 99 percent reduction.

Our data do not identify any add-on controls beyond those we have already considered when promulgating, or proposing revisions to the previous ARV standards in subpart O or finalizing the standards for the previously unregulated ARVs in section IV.B. However, as discussed in section III.F.3 of the proposal preamble (88 FR 22790, April 13, 2023), our evaluation of the performance test data shows that these controls can achieve greater than 99 percent emission reduction.[47] We evaluated 99.9 percent reduction of ARV emissions from facilities using at least 30 tpy of EtO,[48] which is feasible because it is currently achieved by one-third of these facilities. Of these 12 facilities that are currently achieving this emission reduction, nine use catalytic oxidizers, two use a catalytic oxidizer and gas/solid reactor in series, one uses a thermal oxidizer, and one uses a gas/solid reactor. Note that this does not sum to 12 because one facility uses two different types of control systems to reduce its ARV emissions.[49] A 99.9 percent emission reduction would eliminate ARV emissions as a contributor to a facility's MIR to exceed 100-in-1 million for facilities using at least 30 tpy of EtO.[50]

iii. Group 2 Room Air Emissions

There are 13 facilities, all area sources, where revised allowable Group 2 room air emissions contribute to the facilities' MIRs exceeding 100-in-1 million and the EtO usage at these facilities ranges from 4 tpy to 446 tpy.[51] Because Group 2 room air emissions contribute to unacceptable risks from existing area sources in this source category, we evaluated available control options for reducing risks from Group 2 room air emissions.

As discussed in section IV.B of this preamble, we are finalizing a GACT standard for previously unregulated Group 2 room air emissions at existing area source facilities. Specifically, we are finalizing under CAA section 112(d)(5) that area source facilities lower the EtO concentration within each sterilization chamber to 1 ppm before the chamber can be opened.[52] Because there is still unacceptable risk from facilities where EtO usage is above 4 tpy, this requirement will ultimately apply only to existing Group 2 room air emissions at facilities where EtO use is less than 4 tpy.

In evaluating the appropriate GACT standard for previously unregulated existing Group 2 room air emissions at area source facilities, we considered an emission reduction of 80 percent that reflects the use of control devices (Option 1) but did not finalize that option under CAA section 112(d)(5) for reasons stated in section IV.B.3.b. However, having determined under CAA section 112(f)(2) that the risk for the source category is unacceptable, we are determining the emissions standards necessary to reduce risk to an acceptable level without considering costs. We evaluated 80 percent emission reduction of Group 2 room air emissions from area source facilities using at least 4 tpy but less than 20 tpy of EtO. As discussed in section IV.B.3.b of this preamble, 80 percent is the manufacturer guarantee for room air emissions controls provided by one of the commenters. We do not have any performance test data for Group 2 room air emissions at these facilities, so it is unknown whether these sources can achieve greater than 80 percent emission reduction. An 80 percent reduction would eliminate Group 2 room air emissions as a contributor to a facility's MIRs exceeding 100-in-1 million for area source facilities using at least 4 tpy but less than 20 tpy.

For area source facilities using at least 20 tpy, further reduction would be needed to eliminate Group 2 room air emissions as a contributor to a facility's MIR exceeding 100-in-a-million. Our data do not identify any add-on controls beyond those we have already considered when finalizing the standards for the previously unregulated Group 2 room air emission in section IV.B. However, our evaluation of the performance data shows that these controls can achieve greater than 80 percent emission reduction at area source facilities where EtO use is at least 20 tpy. We therefore considered a more stringent Group 2 room air emission standard for these facilities. We evaluated 98 percent reduction of Group 2 room air emissions from area source facilities using at least 20 tpy, which is the emission reduction that has been achieved in one-third of the

[47] While the types of controls used for ARVs are the same as those used for SCVs, the distribution of these controls is different. For example, the use of catalytic oxidizers and gas/solid reactors is more prominent when controlling ARV emissions, while the use wet scrubbers is more prominent when controlling SCV emissions. See memorandum, *Technical Support Document for Proposed Rule—Industry Profile, Review of Unregulated Emissions, CAA Section 112(d)(6) Technology Review, and CAA Section 112(f) Risk Assessment for the Ethylene Oxide Emissions Standards for Sterilization Facilities NESHAP,* located at Docket ID No. EPA–HQ–OAR–2019–0178.

[48] As discussed above, one of the facilities where allowable ARV emissions contribute to the facility's MIR exceeding 100-in-1 million uses 44 tpy. Evaluating the emission reduction for facilities where EtO use is at least 30 tpy provides a sufficient buffer in case the EtO use at this facility drops to below 40 tpy.

[49] As part of the proposed rulemaking, a similar analysis was conducted for ARVs at facilities where EtO use is at least 10 tpy. See section III.F.3.a of the proposal preamble for more details on that analysis (88 FR 22790, April 13, 2023).

[50] As part of the proposed rulemaking, we evaluated a 99.9 percent emission reduction standard for ARVs at facilities where EtO use is at least 10 tpy as part of the technology review (see section III.F.3 of the proposal preamble (88 FR 22790, April 13, 2023)). For existing sources, this option was rejected in favor of a more cost-effective option (*i.e.,* 99.6 percent emission reduction). However, we proposed a 99.9 percent emission reduction standard for new sources pursuant to CAA section 112(d)(6).

[51] As discussed earlier, the EPA has the authority to conduct an (f)(2) review of GACT standards and is exercising that authority in this action.

[52] As discussed in section IV.B of this preamble, we are finalizing an 80 percent emission reduction standard for all new Group 2 room air emissions at area source facilities, regardless of EtO use, under CAA section 112(d)(5).

available performance test runs for these facilities.[53] 98 percent reduction would eliminate Group 2 room air emissions as a contributor to a facility's MIR exceeding 100-in-a-million for area source facilities where EtO use is at least 20 tpy.

iv. CEV Emissions

There is one facility within the source category where revised allowable emissions from CEVs contribute to the facility's MIR exceeding 100-in-1 million, and this is an area source facility that currently uses 446 tpy of EtO. The previous subpart O did not regulate CEVs at area source facilities. As discussed in section IV.B of this preamble, we are finalizing a GACT standard for these sources. Specifically, pursuant to CAA section 112(d)(5), we are finalizing a 99 percent emission reduction standard for CEVs at area source facilities.

Our data do not identify any add-on controls beyond those we have already considered when finalizing the standards for CEVs in section IV.B. However, our evaluation of the performance test data shows that these controls can achieve greater than 99 percent reduction. We therefore considered a more stringent CEV emission standard for area source facilities where EtO use is at least 400 tpy. We evaluated 99.9 percent reduction of CEV emissions from facilities where EtO use is at least 400 tpy, which is the emission reduction that is currently achieved by 75 percent of these facilities.[54] A 99.9 percent reduction would eliminate CEV emissions as a contributer to a facility's MIR exceeding 100-in-1-million for facilities where EtO use is at least 400 tpy.

v. Group 1 Room Air Emissions

There are four area source facilities within the source category where revised allowable Group 1 room air emissions contribute to the facilities' MIRs exceeding 100-in-1 million, and the EtO usage at these facilities ranges from 44 to 446 tpy. The previous subpart O did not regulate Group 1 room air emissions at area source facilities. As discussed in section IV.B of this preamble, we are finalizing a GACT standard for these sources. Specifically, pursuant to CAA section 112(d)(5), we are finalizing an 80 percent emission reduction as the GACT standard for Group 1 room air emissions at area source facilities.

Our data do not identify any add-on controls beyond those we have already considered when finalizing the standards for Group 1 room air emissions in section IV.B. However, our evaluation of the performance test data shows that these controls can achieve greater than 80 percent reduction. We therefore considered a more stringent Group 1 room air emission standard for area source facilities where EtO use is at least 40 tpy. We evaluated 98 percent emission reduction of Group 1 room air emissions from area source facilities using at least 40 tpy, which is the emission reduction that has been achieved in all but one of the six available performance test runs for these facilities.[55] A 98 percent reduction would eliminate Group 1 room air emissions as a contributor to a facility's MIRs exceeding 100-in-1-million for area source facilities where EtO use is at least 40 tpy.

Considering all of the emission reductions that we evaluated above, the source category MIR would be reduced to 100-in-1 million. This means that all facilities would have an MIR at or below 100-in-1 million,[56] and the population exposed to risk levels greater 100-in-1 million would be reduced to zero. In addition, the population exposed to risk levels greater than or equal to 1-in-1 million living within 50 km of a facility would be reduced to between 710,000 (when considering some facilities are currently performing better than the standards) and 1.41 million people (when considering all facilities perform at the level of the standards). Finally, the cancer incidence would be reduced from 0.9 to between 0.1 (when considering some facilities are currently performing better than the standards) and 0.2 (when considering all facilities perform at the level of the standards), or from 1 cancer case every 1.1 years to 1 cancer case every 5 to 10 years. For these reasons, we find that the preceding emission reductions that we evaluated reduce risks to an acceptable level. These emission reduction measures are:

- 99.99 percent emission reduction for SCVs at facilities where EtO use is at least 30 tpy,
- 99.9 percent emission reduction for SCVs at facilities where EtO use is at least 10 tpy but less than 30 tpy,
- 99.8 percent emission reduction for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy,
- 99.9 percent emission reduction for ARVs at facilities where EtO use is at least 30 tpy,
- 99.9 percent emission reduction for CEVs at facilities where EtO use is at least 400 tpy,
- 98 percent emission reduction for Group 1 room air emissions at area source facilities where EtO use is at least 40 tpy,
- 98 percent emission reduction for Group 2 room air emissions at area source facilities where EtO use is at least 20 tpy, and
- 80 percent emission reduction for Group 2 room air emissions at area source facilities where EtO use is at least 4 tpy but less than 20 tpy.

b. Ample Margin of Safety (Step 2)

At step 1 of our review of residual risks under CAA section 112(f)(2), we have identified a suite of standards and determined that they are necessary to reduce risks to an acceptable level. These include standards for SCVs at facilities with EtO usage of at least 1 tpy, ARVs at facilities with EtO usage of at least 30 tpy, CEVs at area source facilities with EtO usage of at least 400 tpy, Group 1 room air emissions at area source facilities with EtO usage of at least 40 tpy, and Group 2 room air emissions at area source facilities with EtO usage of at least four tpy. For step 2 of our review of residual risks, we evaluate whether more stringent standards are necessary to provide an ample margin of safety to protect public health. While we do not consider costs in the step 1 analysis, costs are a factor we consider in the step 2 analysis. For details on the assumptions and methodologies used in the costs and impacts analyses, see the technical memorandum titled *Ample Margin of Safety Analysis for Ethylene Oxide Commercial Sterilization—Promulgation Rule Review for the Ethylene Oxide Commercial Sterilization Source Category,* which is available in the docket for this rulemaking.

As part of the proposed rulemaking, we considered six options (which are identified in the proposal preamble table 22 (88 FR 22829) and proposed Control Options A and C as part of the ample margin of safety analysis. Control Option A would have required 99.94 percent emission reduction for SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy. We are not finalizing Control Option A for the following reasons. First, this option is less stringent than the standard we have

[53] All of these facilities use gas/solid reactors to control their Group 2 room air emissions.

[54] There are three facilities that are currently achieving this emission reduction. Of these three facilities, two use catalytic oxidizers, and one uses a wet scrubber.

[55] All of these facilities use gas/solid reactors to control their Group 1 room air emissions.

[56] Considering actual emissions, most facilities (*i.e.,* 87 out of 88) would have an MIR less than 100-in-1 million.

already identified in Step 1 (99.99 percent emission reduction) for SCV emissions at facilities where EtO use is at least 30 tpy.[57] Second, for facilities where EtO use is less than 30 tpy, we do not have any performance tests showing that these facilities can perform better than the manufacturer guarantee (*i.e.,* 99.9 percent emission reduction for SCVs). For these reasons, we are not finalizing Control Option A as part of this rulemaking. Control Option C would have required 99.8 percent emission reduction for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy. As discussed in section IV.C.2.a of this preamble (step 1 of risk review), Control Option C is one of the standards identified under the revised Step 1 analysis as necessary to reduce risks to an acceptable level.

In addition, we evaluated the following options but rejected them for the reasons discussed below:

○ For ARVs at facilities where EtO use is at least 30 tpy, we do not have data showing that it is technically feasible for all facilities to achieve greater than 99.9 percent emission reduction (which is the standard applicable to these sources that we have determined under step 1 as necessary to reduce risks to an acceptable level).

• For ARVs at facilities where EtO use is less than 10 tpy, we were unable to identify any cost-effective options that achieve emission reduction greater than the current 99 percent emission reduction standard (GACT). More information is presented in the technical memorandum titled *Ample Margin of Safety Analysis for Ethylene Oxide Commercial Sterilization—Promulgation Rule Review for the Ethylene Oxide Commercial Sterilization Source Category,* which is available in the docket for this rulemaking.

• For Group 2 room air emissions at area source facilities where EtO use is at least 20 tpy, we do not have data indicating that it is technically feasible for all facilities to achieve greater than 98 percent emission reduction (which is the standard applicable to these sources that we have determined under step 1 as necessary to reduce risks to an acceptable level).

• For Group 2 room air emissions at area source facilities where EtO use is less than 20 tpy, we do not have any performance tests showing that these facilities can perform better than the manufacturer guarantee (*i.e.,* 80 percent emission reduction for room air emissions, which is the standard for facilities using at least 4 tpy but less than 20 tpy of EtO that we have determined under step 1 as necessary to reduce risks to an acceptable level).

• For Group 2 room air emissions at area source facilities where EtO use is less than 4 tpy, 80 percent emission reduction is not cost effective.[58]

• For Group 1 room air emissions at area source facilities where EtO use is at least 40 tpy, we do not have data indicating that it is technically feasible for all facilities to achieve greater than 98 percent emission reduction (which is the standard for these affected sources that we have identified in Step 1 as necessary to reduce risks to an acceptable level).

• For Group 1 room air emissions at area source facilities where EtO use is less than 40 tpy, we do not have any performance tests showing that these facilities can perform better than the manufacturer guarantee (*i.e.,* 80 percent emission reduction for room air emissions, which we have established in this final rule as the GACT standard for Group 1 room air emissions at these facilities).

However, there are two potential options. One potential option is 99.6 percent emission reduction for ARVs at facilities where EtO use is at least 10 tpy but less than 30 tpy. This is cost effective and is already being achieved by these facilities. The other potential option is to further reduce CEV emissions at area source facilities.[59] Under this option, which would reduce CEV emissions by 99.9 percent at area source facilities where EtO use is at least 60 tpy less than 400 tpy,[60] costs were found to be a $6,820,000 total capital investment and a $1,670,000 total annualized cost. The estimated EtO emissions reductions are 1.9 tpy (*i.e.,* 3,720 lb/year) with a cost effectiveness of $895,000 per ton of EtO (*i.e.,* $448 per lb of EtO). Considering EtO is a highly potent carcinogen, the cost-effectiveness number of this option is within the range of the values that we have determined to be cost-effective for highly toxic HAPs. As explained in section IV.B.3.b of this preamble, this includes hexavalent chromium, where we finalized a requirement with a cost-effectiveness of $15,000/lb ($30,000,000/ton) for existing small hard chromium electroplating to provide an ample margin of safety (taking into account cost among other factors) (77 FR 58227–8, 58239). While we do not know what the full extent of risk reductions would be, we estimate that, compared to the measures in step 1, this control option would further reduce the population exposed to risk levels greater than or equal to 1-in-1 million by additional 10,000–30,000 people. For area sources where EtO use is less than 60 tpy, we do not have any performance test data showing that existing controls can achieve greater than 99 percent reduction for CEVs (which is the GACT standard we have established in this final rule for CEV at area sources). In addition, for area source facilities where EtO use is at least 400 tpy, we were unable to identify any cost-effective options. Therefore, we did not consider a more stringent CEV standard for facilities where EtO use at least 400 tpy.

In the post control scenario (*i.e.,* with the implementation of the standards identified under step 1 and the two potential options discussed immediately above in this step 2 analysis, we estimated that the baseline cancer MIR of 6,000-in-1 million for actual emissions and 8,000-in-1 million for allowable emissions would be reduced to 100-in-1 million, with EtO driving the risk. While the MIR for the source category will be 100-in-1 million, we estimate that most facilities (*i.e.,* 87 out of 88) will have an MIR less than 100-in-1 million. There is an estimated reduction in cancer incidence to 0.2 excess cancer cases per year (or one excess case every 5 years), down from 0.9 excess cancer cases per year (or one excess cancer case every 1.1 years) for baseline actual emissions and down from 8 excess cancer cases per year (or one excess cancer case every 1.5 months) for baseline allowable emissions. We estimate that, after full implementation of this final rule, 0 people would have cancer risks greater than 100-in-1 million, down from 19,000 people for actual emissions and 260,000 people for allowable emissions. In addition, the number of people estimated to have a cancer risk greater than or equal to 1-in-1 million would be reduced to 1.38 million people, down from 8.5 million people for actual emissions and 62 million people for

[57] For facilities where use is less than 30 tpy, we do not have performance test data indicating that 99.99 percent emission reduction for SCVs is technical feasible.

[58] As discussed in section IV.B.3.b of this preamble, we analyzed this option as part of the GACT analysis and found it to be cost-effective. However, this analysis included all facilities in the source category (*i.e.,* not just those where EtO use is less than 4 tpy).

[59] As discussed in section IV.B.3.b of this preamble, pursuant to CAA sections 112(d)(2) and 112(d)(3), we are finalizing a 99.94 percent emission reduction standard for CEVs at major source facilities. We did not identify any cost-effective BTF options.

[60] As discussed in step 1 analysis, pursuant to CAA section 112(f)(2), this standard for CEVs at area source facilities where EtO usage is at least 400 tpy is necessary to reduce risks to an acceptable level.

allowable emissions (table 19 of this preamble).

Again, we note that some facilities are currently performing better than the controls finalized under CAA sections 112(f)(2), and in that case we estimate the maximum lifetime individual cancer risk as 100-in-1 million, with EtO driving the risk. The total estimated cancer incidence is estimated to be 0.1 excess cancer cases per year, or 1 excess case in every 10 years, with approximately 700,000 people estimated to have cancer risks greater than or equal to 1-in-1 million and 0 people estimated to have cancer risks greater than 100-in-1 million (table 19 of this preamble).

TABLE 19—BASELINE AND POST-CONTROL RISK (AFTER CONTROLS PROMULGATED UNDER CAA SECTIONS 112(F)(2) SUMMARY FOR THE COMMERCIAL STERILIZATION FACILITIES SOURCE CATEGORY BASED ON EMISSIONS IN THE FINAL RULE

	Inhalation cancer risk		Population cancer risk		
	Maximum individual risk (in 1 million)	Risk driver	Cancer incidence (cases per year)	>100-in-1 million	≥1-in-1 million
Actual Emissions Baseline Risk	6,000	ethylene oxide	0.9	19,000	8,500,000
Allowable Emissions Baseline Risk	8,000	ethylene oxide	8	260,000	62,000,000
Post-control Risk	100	ethylene oxide	[1] 0.1–0.2	0	[1] 700,000–1,380,000

[1] Ranges in values account for if all facilities were performing at the level of the standards (high end) to considering facilities that are currently performing better than the standards (low end).

Additional details of the analyzed risks can be found in the *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2024 Risk and Technology Review Final Rule,* available in the docket for this rulemaking.

Based on our ample margin of safety analysis, including all health information and the associated cost and feasibility discussed above, we find that requiring the standards that, based on our analysis, would bring risks to an acceptable level, along with 99.6 percent emission reduction for ARVs at facilities where EtO use is at least 10 tpy but less than 30 tpy and 99.9 percent emission reduction for CEVs at area source facilities where EtO use is at least 60 tpy but less than 400 tpy, would provide an ample margin of safety to protect public health.

c. Environmental Effects

As explained in our proposed rule, the emissions data indicate that no environmental HAP are emitted by sources within this source category. In addition, we are unaware of any adverse environmental effects caused by HAP emitted by this source category. Therefore, we do not expect there to be an adverse environmental effect as a result of HAP emissions from this source category. For the reason stated above, it is not necessary to set a more stringent standard to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect.

d. Rule Changes

Based on comments received on the proposed rulemaking, we are finalizing the following emissions standards pursuant to CAA section 112(f)(2):

- 99.99 percent emission reduction for SCVs at facilities where EtO use is at least 30 tpy,
- 99.9 percent emission reduction for SCVs at facilities where EtO use is at least 10 tpy but less than 30 tpy,
- 99.8 percent emission reduction for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy,
- 99.9 percent emission reduction for ARVs at facilities where EtO use is at least 30 tpy,
- 99.6 percent emission reduction for ARVs at facilities where EtO use is at least 10 tpy but less than 30 tpy,
- 99.9 percent emission reduction for CEVs at area source facilities where EtO use is at least 60 tpy,
- 98 percent emission reduction for Group 1 room air emissions at area source facilities where EtO use is at least 40 tpy,
- 98 percent emission reduction for Group 2 room air emissions at area source facilities where EtO use is at least 20 tpy, and
- 80 percent emission reduction for Group 2 room air emissions at area source facilities where EtO use is at least 4 tpy but less than 20 tpy.

We are not finalizing the work practice standards that were proposed for facilities where the MIR remained greater than 100-in-1 million after the imposition of requirements under ''Control Option 1'', which would have required facilities to limit their existing Group 2 room air emissions to a maximum volumetric flow rate of 2,900 dscfm and a maximum EtO concentration of 30 ppbv. We had proposed these standards based on the risk review we conducted during the proposal stage, which has been substantially revised. As discussed above, based on the revised risk review, we are finalizing a different suite of standards pursuant to CAA section 112(f)(2) to reduce risks to an acceptable level and provide an ample margin of safety to protect public health.

3. What key comments did we receive on the risk review, and what are our responses?

This section provides comment summaries and responses for the key comments received regarding our exclusion of allowable emissions from the risk assessment, the control requirements proposed for SCVs, and the work practice standards that were proposed for facilities where the MIR remained greater than 100-in-1 million after the imposition of requirements under ''Control Option 1'' evaluated in the residual risk assessment during the proposal stage, as well as the proposed GACT standards that were incorporated into the residual risk assessment. We received comments against the exclusion of allowable emissions from the risk assessment, the control requirements proposed for SCVs, and the work practice standards that were proposed for facilities where the MIR remained greater than 100-in-1 million after the imposition of requirements under ''Control Option 1.'' Other comments on these issues, as well as on additional issues regarding the residual risk review and our proposed changes based on the residual risk review, can be found in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for*

Commercial Sterilization Facilities, available in the docket for this rulemaking.

Comment: Two commenters contended that we should use allowable emissions when conducting residual risk assessments. One commenter stated that actual emissions only provide a snapshot in time and that there is no legal requirement at the Federal level to maintain emissions beyond the NESHAP requirements in any given year. The commenter also referenced a 2010 Science Advisory Board (SAB) report that recommended we use ''facility-specific allowable emissions reflecting current regulatory limits.'' [61]

Response: We agree with commenters that allowable emissions should be considered as part of the residual risk assessment. As discussed in section III.C of the proposed rulemaking (88 FR 22790), because allowable emissions and risks were higher than actual emissions, and in light of our finding that risks were unacceptable based on actual emissions, we determined that a separate assessment of allowable emissions was unnecessary. However, for the reasons stated by the commenters, we have incorporated allowable emissions into our revised risk assessment as part of this final rulemaking.

Comment: Two commenters expressed the following concerns with the 99.94 percent emission reduction standard for SCVs:

- Our technical publications on reduction ranges for add-on control equipment for HAPs do not show that a destruction and removal efficiency of 99.94 percent is achievable under normal continuous operation.
- The proposed requirement does not require additional controls based on new technology, but requires achieving greater efficiency from existing controls. Specifically, one commenter stated that nothing in the proposal preamble suggests that the control systems installed in order to meet the current SCV standard need to be replaced or their performance upgraded. The commenter further stated that our cost estimates include nothing with respect to controls for SCVs.
- Emission control device manufacturers do not guarantee a destruction removal efficiency of 99.94 percent for SCVs.

Two commenters stated that emissions standards should be based on achievable, manufacturer guaranteed destruction removal efficiency of emission control equipment. One commenter stated that, based on their discussions with control device manufacturers, they believe that the best and most advanced technologies will be guaranteed to meet a 99.9 percent emission reduction standard for SCVs.

Response: We disagree with the commenters that our technical publications on reduction ranges for add-on control equipment for HAPs do not show that an emission reduction of 99.94 percent (and, therefore, any greater emission reduction) is achievable under normal continuous operation for SCVs. Such a performance test was conducted for at least two systems that control SCV emissions, and the reported emission reduction for both of these systems was 99.99 percent. Below is a discussion on the relevant points for each performance test:

- The first performance test was conducted on November 17, 1999.[62] It is unknown what the EtO use at this facility was at the time of the performance test, but it is expected that it was somewhere between 10 tpy and 30 tpy. At the time of the performance test, the facility used a wet scrubber to control its SCV emissions.[63] Prior to November 2, 2001, we required facilities to test the both the first and last evacuations of the SCV. The SCV concentration decreases over time, so any emission reductions between the first and last evacuations are going to be at least as high as that of the last evacuation. For this performance test, the average emission reduction at the first evacuation was 99.9946 percent, and the average emission reduction at the last evacuation was 99.99 percent. This means that the emission reduction over all the SCV cycles exceeded 99.99 percent. While this performance test data is almost 25 years old, emission control technology has continued to improve over time, and emission reductions today are likely higher.
- The data from this performance test indicates that, for facilities where EtO use is at least 30 tpy, any SCV control system that is achieving higher than 99.9946 percent emission reduction on the first evacuation is likely achieving at least 99.99 percent emission reduction overall. Our current performance test data indicates that at least 15 facilities where EtO use is at least 30 tpy are currently achieving greater than 99.9946 percent emission reduction on the first evacuation, and the highest emission reduction on the first evacuation that we have observed is 99.99999982 percent. Of these 15 facilities that are currently achieving this emission reduction, eight use wet scrubbers, three use a wet scrubber and gas/solid reactor in series, two use thermal oxidizers, one uses a catalytic oxidizer, and one uses a wet scrubber and catalytic oxidizer in series.
- The second performance test was conducted on March 10, 11, and 12, 2020,[64] and EtO use at this facility is 229.2 tpy. This facility uses wet scrubbers and gas/solid reactors in series to control its SCV emissions. Due to the configuration of the control system at this facility, there is no mechanism to test the SCVs on their own. Therefore, this performance test was conducted for all emission sources at the facility. For lower concentration streams like ARVs, CEVs, and room air emissions, emission reductions tend to be lower. Therefore, it is likely that the SCV emission reduction at this facility exceeds 99.99 percent.

As a general matter, it is not our policy to simply rely on manufacturer guarantees when setting or revising emission standards. Typically, we evaluate performance tests to see what the controls are actually achieving in practice and then set or revise the standards based on that evaluation. However, if representative performance test data are not available, then manufacturer guarantees may be considered. We also note that it is common within this industry to combine different types of control devices in series when reducing emissions. Since these control devices are often made by different manufacturers, there is no manufacturer guarantee available for these systems. We do not share the commenters' concerns that emission control device manufacturers do not guarantee a destruction removal efficiency of 99.94 percent for SCVs, as representative performance test data is available and indicates that these emission reductions (and, in fact, higher emission reductions) are achievable for higher use facilities. However, such performance test data are not available for smaller users, and it is not known whether those facilities can meet the emission reduction that the higher use facility is demonstrating. Therefore, we agree with commenters that consideration of manufacturer guarantees is warranted for lower use facilities, and the

[61] Commenter provided the following reference: EPA Science Advisory Board, Review of EPA's draft entitled, ''Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board with Case Studies—MACT I Petroleum Refining Sources and Portland Cement Manufacturing'', at ii, (May 7, 2010), *https://www.regulations.gov/document/EPA-HQ-OAR-2010-0682-0103.*

[62] *https://www.regulations.gov/document/EPA-HQ-OAR-2019-0178-0297.*

[63] This facility continues to use a wet scrubber to control its SCV emissions to this day.

[64] *https://www.regulations.gov/document/EPA-HQ-OAR-2019-0178-0349.*

standards that we are finalizing for SCVs at facilities where EtO use is less than 30 tpy do not exceed the manufacturer guarantee.

In addition, we disagree with one commenter's assertion that there is nothing in the proposal preamble to suggest that the control systems installed in order to meet the current SCV standard need to be replaced or their performance upgraded. Furthermore, the commenter's assertion that our cost estimates include nothing with respect to controls for SCVs is incorrect. As discussed in section II.A of this preamble, under the first step of the residual risk assessment, if risks are unacceptable, the EPA must determine the emissions standards necessary to reduce risk to an acceptable level without considering costs. While we did not conduct a cost analysis for the SCV standards that we are finalizing pursuant to CAA section 112(f)(2) step 1 (risk acceptability analysis), we assume that new controls would be needed in order to achieve those standards, and the cost of those controls are included in the total costs of the rule. However, we note that the final standard is simply an emission reduction standard, and owners and operators may choose to meet the standard however they see fit (*e.g.,* either through process changes, the replacement of a control system, or the use of additional control devices to further reduce emissions from an existing control system). In some cases, existing controls may already be achieving the standard, and in that case, no changes are required.

Comment: Several commenters stated that reducing the volumetric flow rate from Group 2 room air emissions to 2,900 dscfm would be detrimental to sterilization operations and may make it impossible to achieve the proposed PTE requirement.

Response: Based on comments received on the proposed rulemaking, we revised the risk assessment, which resulted in different emission reduction measures than what we proposed to bring the risk to the acceptable level. The proposed work practice standards are no longer necessary to bring the MIR of Group 2 room air emissions at area source facilities to 100-in-1 million. Therefore, we are not including a work practice standard that would require any facilities to reduce their throughput as part of this final rule.

4. What is the rationale for our final approach and final decisions for the risk review?

As noted in our proposal, we set standards under CAA section 112(f)(2) using ''a two-step standard-setting approach, with an analytical first step to determine an 'acceptable risk' that considers all health information, including risk estimation uncertainty, and includes a presumptive benchmark on MIR of approximately 1-in-10 thousand'' (88 FR 22790, April 13, 2023; see also 54 FR 38045, September 9, 1989). We weigh all health risk factors in our risk acceptability determination, including the cancer MIR, cancer incidence, the maximum TOSHI, the maximum acute HQ, the extent and the distribution of cancer and noncancer risks in the exposed population, multipathway risks, and the risk estimation uncertainties. In the second step of the approach, the EPA considers whether the emissions standards provide an ample margin of safety to protect public health ''in consideration of all health information, including the number of persons at risk levels higher than approximately 1-in-1 million, as well as other relevant factors, including costs and economic impacts, technological feasibility, and other factors relevant to each particular decision.'' *Id.* The EPA must promulgate emission standards necessary to provide an ample margin of safety to protect public health or determine that the standards being reviewed provide an ample margin of safety without any revisions. After conducting the ample margin of safety analysis, we consider whether a more stringent standard is necessary to prevent an adverse environmental effect, taking into consideration costs, energy, safety, and other relevant factors.

Since proposal, our determinations regarding risk acceptability, ample margin of safety, or adverse environmental effects have not changed. The revised risk assessment (see document, *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2024 Risk and Technology Review Final Rule,* which is available in the docket for this rulemaking) shows that, after application of controls finalized in this rulemaking, the MIR for the source category is 100-in-1 million. Therefore, after application of the controls for SCVs at facilities where EtO use is at least 1 tpy, ARVs at facilities where EtO use is at least 30 tpy, CEVs at area source facilities where EtO use is at least 400 tpy, Group 1 room air emissions at area source facilities where EtO use is at least 40 tpy, and Group 2 room air emissions at area source facilities where EtO use is at least four tpy, we find that the risks are acceptable and that the final standards will achieve an ample margin of safety to protect public health.

D. Technology Review for the Commercial Sterilization Facilities Source Category

1. What did we propose pursuant to CAA section 112(d)(6) for the Commercial Sterilization Facilities source category?

Based on our technology review for the Commercial Sterilization Facilities source category, we proposed under CAA section 112(d)(6) changes to the standards for SCVs where EtO use is at least 10 tpy, SCVs where EtO use is at least 1 tpy but less than 10 tpy, and ARVs where EtO use is at least 10 tpy. We provide a summary of our findings, as proposed, in this section. In general, while the types of controls have essentially remained the same since promulgation of subpart O, available information show greater emission reduction since then for some of these control options.

For SCVs, we proposed the following emission standards pursuant to CAA section 112(d)(6):

- 99.94 percent reduction for new and existing SCVs at facilities where EtO use is at least 10 tpy, and
- 99.8 percent reduction for new and existing SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy.

These are the maximum SCV emission reductions with which compliance can be demonstrated. We evaluated these standards against the maximum SCV emission reductions that all facilities are currently meeting within each subcategory. For more information, see sections III.F.1 and III.F.2 of the proposal preamble (88 FR 22790, April 13, 2023).

For ARVs, we proposed the following emission standards pursuant to CAA section 112(d)(6):

- 99.6 percent emission reduction for existing ARVs at facilities where EtO use is at least 10 tpy, and
- 99.9 percent emission reduction for new ARVs at facilities where EtO use is at least 10 tpy.

These are the emission reductions that have been demonstrated by 75 percent and 50 percent of all available performance tests, respectively. We evaluated both emission reductions for new and existing ARVs. For more information, see section III.F.3 of the proposal preamble (88 FR 22790, April 13, 2023).

2. How did the technology review change for the Commercial Sterilization Facilities source category?

We are finalizing the following emission standards as a result of the

technology review for the Commercial Sterilization Facilities source category, as proposed:

- 99.8 percent emission reduction for new and existing SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy,
- 99.6 percent emission reduction for existing ARVs at facilities where EtO use is at least 10 tpy, and
- 99.9 percent emission reduction for new ARVs at facilities where EtO use is at least 10 tpy.

For new and existing SCVs at facilities where EtO use is at least 10 tpy, based on comments received on the proposal, we are finalizing a 99.9 percent emission reduction, which is the manufacturer guarantee. There is a lack of representative performance test data for these SCVs, and we are unable to determine whether all facilities can achieve an emission reduction higher than the manufacturer guarantee. For more information, see section IV.D.3.a of this preamble.

3. What key comments did we receive on the technology review, and what are our responses?

This section provides comment and responses for the major comments on our proposed CAA section 112(d)(6) standards. Other comment summaries and our responses for additional issues raised regarding these activities, as well as issues raised regarding our proposed revisions, can be found in the document *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* available in the docket for this rulemaking.

a. SCVs at Facilities Where EtO Use Is at Least 10 tpy

Comment: Several commenters questioned whether the proposed emission standards for SCVs at facilities where EtO use is at least 10 tpy could be achieved with existing technology and stated that we should consider manufacturer guarantees when revising the standard, along with a maximum concentration limit. The commenters stated that we arrived at a 99.94 percent emission reduction standard based on performance tests that used the previous testing procedures in Subpart O. These consisted of one-hour test runs that occurred during the initial vacuum event, when EtO loading to the control system (and, therefore, emission reduction) is high. The commenters further stated that we proposed extending the duration of each test run to 24 hours, which would cover a variety of operating conditions, including periods of low inlet concentration, which have not been required to be tested. The commenters contended that the performance test results based on the proposed testing procedures would be lower than those under the previous testing procedures. One commenter stated that there are no data confirming whether state-of-the-art control systems can meet a 99.94 percent emission reduction standard for SCVs where each performance test run is 24 hours, and another commenter stated that we must ensure that any required emission reduction standards that are finalized for SCVs are proven and achievable as part of performance tests consisting of 24-hour test runs. One commenter stated that, based on their discussions with control device manufacturers, they believe that the best and most advanced technologies will be guaranteed to meet a 99.9 percent emission reduction standard for SCVs.

Response: We agree with the commenters that it is not appropriate to use performance test data based on the previous testing procedures in Subpart O to justify revisions to the emission standards for SCVs. We disagree with one commenter's statement that there are no data confirming whether state-of-the-art control systems can meet a 99.94 percent emission reduction standard for SCVs where each test run is 24 hours. As discussed in section IV.C.3, such data exist for at least one system that controls SCV emissions. However, the EtO usage at this facility is fairly high, and we are unable to determine whether smaller users can meet this emission standard. With respect to the suggestion by some commenters that we consider a manufacturer guarantee reduction level, which one commenter stated is 99.9 percent emission reduction for SCVs, we have no data disputing such level or reason to question the manufacturer's guarantee. Further, as discussed in our response to the next comment below, we find the cost of this option to be reasonable. Therefore, pursuant to CAA section 112(d)(6), we are finalizing a 99.9 percent emission reduction standard for SCVs at facilities where EtO use is at least 10 tpy.[65]

We disagree with the commenter's suggestion that we should consider a maximum concentration limit along with the percentage reduction standard. As discussed in section IV.B.3.a, we are concerned that some owners and operators may dilute the air flow of the emissions stream to meet a concentration standard, which would not result in any actual emission reductions. Furthermore, it is not appropriate to establish upper-bound limitations on air flow within this source category, as additional flow may be necessary in order to mitigate any potential safety issues that may arise. Therefore, we are not finalizing any concentration standards as part of this rulemaking.

Comment: One commenter stated that, for the SCV technology rule under CAA section 112(d)(6), we merely referred back to, and repeated the proposed standards of, the residual risk review. The commenter further stated that we did not conduct the technology review as a separate analysis, but rather, it was inseparably intertwined with the residual risk review. Finally, the commenter stated there is no true technology review in the record and that cost considerations of the proposed CAA section 112(d)(6) emissions standard for existing SCVs at facilities where EtO use is at least 40 tpy were never considered, even though section 112(d)(6) requires considerations of cost.[66]

Response: We disagree with the commenter's statement that a ''true'' technology review was never conducted. In the proposal preamble (88 FR 22839–41), the EPA discussed control options that can achieve further emission reductions compared to the existing subpart O standards. While the types of controls have essentially remained the same, available information shows improvement in emission reduction potential for some of these control options, which we consider to be a development in control technologies; we analyzed this development and proposed revisions to the standards pursuant to CAA section 112(d)(6). The commenter appears to take issue with the fact that these are the same options as those we evaluated under CAA section 112(f)(2), specifically under step 2 (ample margin of safety) analysis. However, in evaluating whether we can achieve further emission reduction and thus lower risks, we naturally would

[65] We also note that, as discussed in section IV.F.3 of this preamble, we are finalizing a requirement for owners and operators to include a representative performance test period for SCVs, along with a justification, in their stack test protocol, so that the delegated authorities can review and approve or deny the protocol as appropriate. This will ensure that performance tests provide a more accurate representation of SCVs emission reductions.

[66] In support of its comment that control costs must be considered under section 112(d)(6) review, the commenter cited to *Nat'l Ass'n for Surface Finishing,* 795 F.3d at 5 (''in the technology review, EPA periodically assess, no less often than every eight years, whether standards should be tightened in view of developments in technologies and practices since the standard's promulgation or last revision, and, in particular, the cost and feasibility of developments and corresponding emissions savings'').

consider controls that reflect the current developments in processes and technology by this industry (*i.e.,* well performing air pollution control), which we are also required to evaluate under CAA section 112(d)(6). For the reason stated above, we find the comment that our technology review was not a ''true'' review to be without merit.

We acknowledge that in proposing a 99.94 percent standard pursuant to CAA section 112(d)(6) for SCV at facilities using at least 10 tpy EtO, we inadvertently evaluated the control costs for facilities using between 10 to 40 tpy only. However, as discussed in our comment response above, we no longer consider the proposed 99.94 percent emission reduction standard to be appropriate. As suggested by several commenters, we evaluated a manufacturer guarantee. Based on one commenter's discussions with control device manufacturers, the best and most advanced technologies will be guaranteed to meet 99.9 percent emission reduction for SCVs. The impacts of this option and the 99.6 percent reduction option that we considered during the proposal stage are presented below in table 20 for existing sources:

TABLE 20—NATIONWIDE EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(6) FOR EXISTING SCVS AT FACILITIES WHERE ETO USE IS AT LEAST 10 TPY

Option	Standard evaluated	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99.9 percent emission reduction	$1,840,000	$752,000	1.14 [2,280 lb]	$661,000 [$330/lb].
2	99.6 percent emission reduction	0	0	0	N/A.

Based on the estimates above, and considering EtO is a highly potent carcinogen, the cost-effectiveness number of this option is within the range of the values that we have determined to be cost-effective for highly toxic HAPs. As explained in section IV.B.3.b of this preamble, this includes hexavalent chromium, where we finalized a requirement with a cost-effectiveness of $15,000/lb ($30,000,000/ton) for existing small hard chromium electroplating to provide an ample margin of safety (taking into account cost among other factors) (77 FR 58227–8, 58239). As part of the proposed rulemaking, the highest cost-effectiveness number that we found was $19,420,188/ton. We did not receive adverse comment on our finding that this is cost-effective. While Option 2 would prevent backsliding, it does not achieve additional emission reduction. Therefore, pursuant to CAA section 112(d)(6), we are revising the standard to require facilities where EtO use is at least 10 tpy to reduce their emissions from existing SCVs by 99.9 percent.

The impacts of these options for new sources, which are presented in table 21 of this preamble, are based on a model plant for new SCVs at a facility using at least 10 tpy of EtO with the following assumptions reflecting the average of each of the parameters at existing facilities using at least 10 tpy of EtO:

- Annual EtO use: 120 tpy.
- Annual operating hours: 8,000.
- Portion of EtO going to SCVs: 94.41 percent.
- SCV flow rate: 200 cfs.

TABLE 21—NATIONWIDE EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(6) FOR NEW SCVS AT FACILITIES WHERE ETO USE IS AT LEAST 10 TPY

Option	Standard evaluated	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99.9 percent emission reduction	$523,000	$136,000	1.02 [2,040 lb]	$134,000 [$67/lb].
2	99.6 percent emission reduction	348,000	106,000	0.68 [1,360 lb]	158,000 [$79/lb].

Based on the estimates above, we find both options to be cost effective. Option 1 would achieve greater emission reductions than Option 2, and Option 1 would be more cost-effective. Therefore, pursuant to CAA section 112(d)(6), we are revising the standard to require facilities where EtO use is at least 10 tpy to reduce their emissions from new SCVs by 99.9 percent.

Comment: In response to the EPA's solicitation of comment on whether to include a mass emission rate standard as an alternative to the percent emission reduction standard, two commenters were opposed to such an alternative. One commenter stated that mass emission rate standards for individual vents do not account for variability between facilities or variability within facilities. The commenter also stated that any standard that fails to reflect individual facility dynamics that materially affect the ability to comply is inappropriate and not achievable.

Response: We agree with the commenters' concerns regarding the alternative, equivalent mass rate emission standards. Therefore, they are not included in this final rule.

b. SCVs at Facilities Where EtO Use Is at Least 1 Tpy but Less Than 10 Tpy

Comment: One commenter stated that they support emission reduction standards based on manufacturer guarantees for control equipment, along with a maximum concentration limit, to ensure that compliance can be achieved and demonstrated. In addition, the commenter did not agree with our method to calculate alternative, equivalent mass rate emission standards. Another commenter stated that, based on their discussions with control device manufacturers, they believe that the best and most advanced technologies will be guaranteed to meet a 99.9 percent emission reduction standard for SCVs.

Response: We agree with the commenter's suggestion that manufacturer guarantees be considered when finalizing the standard. Most of the performance tests that are currently available for SCVs are based on the previous testing procedures, which are not reflective of actual operating conditions. The one performance test we have that is based on actual operating conditions is for a facility

where EtO use exceeds 30 tpy and thus not appropriate for the group of facilities at issue here (*i.e.,* those using at least 1 tpy but less than 10 tpy of EtO). Therefore, a manufacturer guarantee is appropriate to consider in this instance, and a 99.8 percent emission reduction standard falls within the manufacturer guarantee range for SCV controls as provided by one of the commenters (99.9 percent emission reduction). However, this does not change our rationale for a 99.8 percent reduction standard during the proposal stage, which was that this is the maximum emission SCV reduction with which compliance can be demonstrated at all facilities where EtO use is at least 1 tpy but less than 10 tpy considering current emission profiles.

We disagree with the commenter's recommendation for a maximum concentration limit. As discussed in section IV.B.3.a, we are concerned that some owners and operators may dilute the air flow of the emissions stream to meet a concentration standard, which would not result in any actual emission reductions. Furthermore, it is not appropriate to establish upper-bound limitations on air flow within this source category, as additional flow may be necessary in order to mitigate any potential safety issues that may arise. Finally, as discussed in section IV.D.3.a, we are not including any alternative, equivalent mass rate emission standards in the final rule. Therefore, the commenter's concerns regarding the methodology used to calculate the limits are no longer relevant.

c. ARVs at Facilities Where EtO Use Is at Least 10 Tpy

Comment: Several commenters objected to the proposed emission reduction standards and stated that they are not achievable as written. One commenter stated that we should require emission reduction standards based on manufacturer guarantees, along with a maximum concentration limit. Another commenter stated that sterilization is a batch process and that the concentration from the aeration area is subject to constant fluctuation due to differences in product, cycles, facility design, and EtO decline curve, which makes a consistent emission reduction challenging to determine. Finally, several commenters expressed concerns with the use, and our development, of the alternative, equivalent mass rate emission standards due to the wide variations in ARV parameters across this group of facilities, as well as the difficulty in demonstrating compliance with this standard for larger facilities.

Response: We disagree with the commenters' position that the proposed emission reduction standards are not achievable. As discussed in section III.F.3.a of the proposal preamble (88 FR 22790, April 13, 2023), most existing sources (*i.e.,* 75 percent) are already achieving 99.6 percent emission reduction. In addition, 99.9 percent emission reduction has been demonstrated by 50 percent of existing sources. We also disagree with one commenter's suggestion that manufacturer guarantees be considered in this instance for two reasons. First, there is no need to rely on manufacturer guaranteed emission levels because there are available performance test data for ARVs that are representative of actual operating conditions. Unlike SCVs, which go through different active phases with wildly varying concentrations, fluctuations in ARV concentrations are slight; an aeration room serves one purpose, which is to hold product at an elevated temperature, and the resulting ARV concentration is relatively constant. Therefore, a one-hour test period for this source is appropriate, and the resulting performance test data are representative of actual operating conditions. To that end, we disagree with another commenter's statement that fluctuations in the ARV make it difficult to comply with an emission reduction standard. Second, performance test data for ARVs are plentiful. As discussed in section III.F.3.a of the proposal preamble, there are 47 facilities where EtO use is at least 10 tpy, 41 of which have ARVs. Of these 41 facilities, 32 (78 percent) have performance test data. Because the performance test data from ARVs at these facilities are both plentiful and representative of actual operating conditions, there is no need to rely on a manufacturer guaranteed emission reduction level in this instance. We also disagree with the commenters' recommendation for a maximum concentration standard. As discussed in section IV.B.3.a, we are concerned that some owners and operators may dilute the air flow of the emissions stream to meet a concentration standard, which would not result in any actual emission reductions. Furthermore, it is not appropriate to establish upper-bound limitations on air flow within this source category, as additional flow may be necessary in order to mitigate any potential safety issues that may arise. Finally, with respect to the alternative equivalent mass rate emission standards, we agree with the commenters' concerns, and we are not including these standards in the final rule.

Comment: One commenter stated that if the lowest practicably measured concentration is 30 ppbv (our presumed workable-in-practice detection limit for CEMS), then a source with an inlet concentration that is too low will be unable to show the required emission reduction, even if the control system is providing that level of reduction, because the monitoring approach will be unable to distinguish the true outlet concentration from 30 ppbv. The commenter further stated that existing sources would need to have pre-control aeration room concentrations of at least 7.5 ppmv to make this demonstration. Two commenters stated that the increased 99.6 percent (existing facilities) or 99.9 percent (new facilities) ARV emission reduction standards penalize facilities that have reduced EtO concentrations during the sterilization cycle. Several commenters noted that facilities have reduce EtO concentrations during the sterilization cycle (*i.e.,* use of vacuum and/or nitrogen wash cycles) prior to moving the sterilized load to aeration to reduce inlet ARV concentrations, and that removals, on a percent basis, are only achievable with elevated inlet concentrations.

Response: One commenter is correct that, given the lowest practicable measured concentration (30 ppbv), the pre-control concentration would need to be 7.5 ppmv in order to demonstrate compliance with the proposed standard for existing sources. The performance test data that are available for ARVs at these facilities consist of 86 test runs. Of these 86 test runs, only five (six percent) had a measured concentration less than 7.5 ppmv, which suggests low likelihood that facilities will have difficulty demonstrating compliance due to low pre-control concentration. based on the current operating conditions Furthermore, regarding the comment that these standards would penalize sources who have already worked to reduce their EtO concentrations during sterilization and, by extension, their inlet ARV concentrations, as discussed in section III.F.3 of the proposal preamble, 75 percent of existing sources are already meeting the proposed standard; it is unclear, and the commenter does not explain, why a requirement that retains facilities' status quo is a punishment to those facilities. Most of the industry is either (1) currently meeting the proposed standard or (2) capable of meeting the proposed standard based on current operating conditions. In addition, if a facility with existing ARVs

wishes to further reduce their EtO concentrations during sterilization, then operational changes can be made to the aeration room so that the facility can continue to demonstrate compliance with the emission reduction standard. Since new facilities are not currently in operation, there has been no reduction in EtO concentrations during sterilization and, therefore, no penalty has been incurred.

4. What is the rationale for our final approach for the technology review?

Our technology review focused on the identification and evaluation of developments in practices, processes, and control technologies that have occurred since the standards for Commercial Sterilization Facilities were originally promulgated on December 6, 1994 (59 FR 62585) and further amended on November 2, 2001 (66 FR 55577). Specifically, we focused our technology review on all previous standards for the various emission sources in the Commercial Sterilization Facilities source category, including SCVs at facilities where EtO use is at least 10 tpy, SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, and ARVs at facilities where EtO use is at least 10 tpy. In the proposal, we identified developments for all emission sources, and we proposed to revise the standards for these emissions sources under the technology review. Further information regarding the technology review can be found in the proposed rule (88 FR 22790, April 13, 2023) and in the supporting materials in the rulemaking docket at Docket ID No. EPA–HQ–OAR–2019–0178.

During the public comment period, we received several comments on our proposed determinations for the technology review. No information presented by commenters has led us to change our proposed determination under CAA section 112(d)(6) for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy and ARVs at facilities where EtO use is at least 10 tpy, and we are finalizing the changes to those standards as proposed. For SCVs at facilities where EtO use is at least 10 tpy, based on comments received on the proposal, we are finalizing a 99.9 percent emission reduction standard, which is the manufacturer guarantee. There is at least one representative performance test available for SCVs, but it was conducted at a facility with a higher EtO usage rate, and we are unable to determine whether smaller facilities can achieve the emission reduction from that performance test. The key comments and our specific responses can be found in section IV.D.3 of this preamble and in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* available in the docket for this rulemaking.

E. Amendments Addressing Emissions During Periods of SSM

1. What amendments did we propose to address emissions during periods of SSM?

For all emission points in the Commercial Sterilization Facilities source category, we proposed eliminating the SSM exemptions and to have the standards apply at all times. More information concerning the elimination of SSM provisions is in section III.G. of the proposal preamble (88 FR 22790, April 13, 2023).

2. How did the SSM provisions change since proposal?

We are finalizing the SSM provisions as proposed (88 FR 22790, April 13, 2023).

3. What key comments did we receive on the SSM revisions and what are our responses?

This section provides comment summaries and responses for the key comments received regarding our proposed revisions. Other comment summaries and the EPA's responses for additional issues raised regarding these activities as well as issues raised regarding our proposed revisions can be found in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* available in the docket for this rulemaking.

Comment: One commenter stated that the EPA should consider other approaches to adequately account for SSM contingencies. The commenter suggested that the EPA classify sources in SSM states as sub-sources subject to different emissions limitations or work practice standards. Another commenter stated that EtO sterilizers do not create emissions during startup or shut down because, unlike other industrial processes regulated under the NESHAP program, EtO is not emitted as a byproduct of combustion or chemical reaction but is released intentionally in a highly controlled manner. The commenter further stated that sterilization never begins before control equipment is activated and always ends before control equipment is deactivated. Similarly, another commenter stated that the EPA inaccurately assumed that startup and shutdown are no different than normal operation. The commenter further stated that constructing and starting new abatement equipment includes periods of troubleshooting and acceptance testing. The commenter also stated that the proposal does not address the permit-to-construct process and related requirements before transferring to an operating permit. Finally, one commenter suggested that the malfunction exemption should not be eliminated because, due to the nature of sterilization operations and various stages of cycles, commercial sterilizers must be able to address malfunctions that could result in a potential risk to employees or the facility without the risk of being in noncompliance.

Response: As discussed in section III.G.1 of the proposal preamble (88 FR 22790, April 13, 2023), it is common practice in this source category to start an air pollution control device (APCD) prior to startup of the emissions source it is controlling, so the APCD would be operating before emissions are routed to it, which has been confirmed by one of the commenters. In addition, based on responses to the December 2019 questionnaire and the September 2021 ICR, many facilities already have measures in place to ensure that the emission standards are met during periods of SSM, including holding emissions within the process unit or the APCD itself, or the use of onsite generators in the event of a power outage.[67] The comments provided do not support establishing emission standards that apply only during periods of SSM. With respect to classifying sources in SSM states as sub-sources subject to different emissions limitations or work practice standards, the commenter does not provide any rationale for why this should be done or any suggestions for what those emission standards should be. With respect to emission spikes from troubleshooting control devices, as discussed in section IV.F.3 of this preamble, the EPA is finalizing a requirement for emission limits to be based on 30-operating day rolling sums of EtO entering the control system(s) for EtO CEMS, which will help to mitigate these spikes over time. However, the commenter does not provide any rationale for why the permitting process should be considering when evaluating SSM. Finally, we cannot agree with the commenter's recommendation to keep the malfunction exemption in

[67] See memorandum, *Review of Startup, Shutdown, and Malfunction of Process and APCD Equipment in the Ethylene Oxide Commercial Sterilization Source Category Technology Review Project,* located at Docket ID No. EPA–HQ–OAR–2019–0178.

contradiction with *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), in which the court vacated two provisions that exempted sources from the requirement to comply with otherwise applicable CAA section 112(d) emission standards during periods of SSM. As discussed in section III.G.1 of the proposal preamble, in its 2008 decision in *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), the court held that emissions standards or limitations must be continuous in nature, which means that there cannot be exemptions for periods of malfunction. Further, while the EPA could consider establishing a different standard during malfunction if warranted and still be consistent with the *Sierra Club* decision, the commenter does not provide any specific information regarding instances where compliance with the standards during malfunction could result in potential risks to the employees or the facility or suggestions for what emission standards the EPA should consider to address the concern. Therefore, the EPA is not finalizing any emission standards that apply only during periods of SSM.

Comment: One commenter stated that a specific area of concern is the ability to demonstrate compliance during startup and shutdown, asserting that the proposed rule offered no means for a source to remain in compliance during the inevitable and foreseeable, but not predictable, failure of monitoring equipment. The commenter further suggested that the EPA should consider specific reporting and monitoring alternative requirements for these scenarios. The commenter provided the example of a requirement specific to releases from sterilizer pressure relief devices (PRDs) resulting from malfunctions or required during shutdown events that the commenter suggested could be modeled after recent PRD requirements in 40 CFR 63.648(j). Another commenter recommended that facilities should only be required to report malfunction events that result in unpermitted releases to the atmosphere. The commenter stated that, in the example situation where control equipment unexpectedly goes offline during operations but EtO remains trapped within the facilities ducts under negative pressure, there would be no need to create additional administrative compliance requirements for the facility.

Response: With respect to accounting for the failure of monitoring equipment when demonstrating compliance, as discussed in section IV.F.3 of this preamble, the EPA is finalizing a minimum data availability requirement of 90 percent for EtO CEMS. With respect to specific reporting and monitoring alternative requirements that apply during periods of SSM, the commenter did not provide any recommendations for what those requirements should be. In addition, we agree with one commenter's suggestion that facilities should only be required to report malfunction events that result in unpermitted releases to the atmosphere. However, to be clear, we are finalizing reporting requirements for malfunction events that occur with emissions or parametric monitoring equipment.

Comment: One commenter suggested that the EPA should not include the general duty clause in the final rule. The commenter stated that it is not clear on what basis the EPA is claiming authority to impose a general standard of behavior on regulated sources. The commenter asserted that CAA section 112 grants the EPA authority to set emissions limits and certain specific alternative standards but does not grant authority to impose a ''vague and subjective code of conduct.'' The commenter stated that the general duty clause is redundant to proposed amendment to 40 CFR 63.632(b) that would require compliance ''at all times.'' The commenter asserted that if compliance with the specific requirements of the rule will satisfy the general duty, then there is no need for the EPA to reserve the authority to evaluate a source's good air pollution control practices. Furthermore, the commenter asserted that the general duty provisions date back to a regulatory period during which air quality control rules lacked the specificity of monitoring, reporting, and recordkeeping that are included in the proposed rule. The commenter suggested that either the EPA should not finalize the proposed general duty clause at 40 CFR 63.632(j) or that the general duty clause from the General Provisions should be incorporated. The commenter stated that the General Provision contains language that more clearly explains the EPA's exercise of enforcement discretion during SSM periods.

Response: As part of the proposed rulemaking, we proposed to add the following general duty clause to 40 CFR 63.362(j):

''At all times, you must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require the owner or operator to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether a source is operating in compliance with operation and maintenance requirements will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.''

We disagree with the commenter's suggestion to not finalize the general duty clause. We do not consider this duty clause to be redundant just because the emission standards apply at all times; the provision imposes a general duty to operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. Commenters did not provide data supporting the suggestion that this general duty clause is redundant. Even assuming it were redundant, which it is not, the commenter does not explain why it must be removed. In addition, the inclusion of a general duty clause like the one proposed is standard practice for other NESHAPs. Furthermore, we disagree with the commenter's suggestion to incorporate the general duty clause from Subpart A. As discussed in earlier in this section, in its 2008 decision in *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), the court held that under section 302(k) of the CAA, emissions standards or limitations must be continuous in nature, which means that there cannot be exemptions for periods of SSM. The general duty clause in Subpart A contains certain exemptions for periods of SSM. We are therefore finalizing the general duty provision as proposed.

4. What is the rationale for our final approach and final decisions to address emissions during periods of SSM?

We evaluated all of the comments on the EPA's proposed amendments to the SSM provisions. As explained in section III.G of the proposed rule (88 FR 22790, April 13, 2023), in its 2008 decision in *Sierra Club* v. *EPA,* the court held that under CAA section 302(k), emissions standards or limitations must be continuous in nature and that the SSM exemption violates the CAA's requirement that some CAA section 112 standards apply continuously. In addition, as part of this rulemaking, we have gathered information that indicates many facilities already have measures in place to ensure that the emission standards are met during periods of

SSM. Therefore, we determined that these amendments, which remove and revise provisions related to SSM, are necessary to be consistent with the requirement that the standards apply at all times. More information concerning the amendments we are finalizing for SSM is in the preamble to the proposed rule and in the comments and our specific responses to the comments in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* available in the docket for this rulemaking. Therefore, we are finalizing our approach for the SSM provisions as proposed.

F. Other Amendments to the Standards

1. What other amendments did we propose for the Commercial Sterilization Facilities source category?

We proposed that owners and operators would be required to demonstrate compliance via annual performance testing and parametric monitoring of EtO through the use of CEMS. As discussed in section III.G.2.c of the proposal preamble (88 FR 22790, April 13, 2023), we did not propose to include requirements for fenceline or ambient air monitoring as part of this rule for the following reasons:

- Typically for this type of monitoring, we require the fenceline monitor to be located at least 50 meters from the source of emissions to allow for some dispersion.
- In contrast to the large number of dispersed and difficult-to-monitor emission points for other source categories for which we have either finalized or proposed fenceline monitoring requirements (*e.g.,* refineries), current room air releases at commercial sterilization facilities are typically at ground-level and consist of uncontrolled building emissions through doorways, loading points, and ventilation exhausts, all of which can be captured while inside the building and routed through a vent to a control device.
- The proposed PTE design criteria, room air emission standards, and associated parametric monitoring would effectively and continuously ensure these previously uncontrolled emissions are captured and routed to exhaust points that are then subject to removal or emission rate standards.

With respect to fenceline monitoring, we solicited comment on (1) whether fenceline monitoring should be required regardless of the proposed PTE design criteria, proposed room air emission standards, and proposed continuous parametric monitoring; (2) the technical feasibility of fenceline monitoring and available technology able to measure at any potential action level; and (3) the potential cost of continuous fenceline monitoring and associated work practices if implemented.

With respect to ambient air monitoring, we solicited comment on how this could be used to screen for elevated concentrations of EtO above the ambient baseline and how this information could be used to trigger a root cause analysis to identify potential source(s) of emission and to perform corrective action, if a potential source of the emissions was part of an affected source under the commercial sterilization proposed rule. We also solicited comment on (1) the feasibility of other types of air monitoring that could be applied to this sector for compliance assurance and the costs associated with this type of monitoring, (2) how frequently this monitoring should occur, (3) the recordkeeping and reporting requirements for this type of monitoring, and (4) how should any action-level be defined.

We proposed various changes to the performance testing requirements to ensure that the results are as accurate as possible, including the approved test methods, requirements for SCV inlet testing, and 24-hour test runs for larger users. Furthermore, we proposed various changes to the parametric monitoring requirements, as well as requirements for demonstrating continuous compliance with the PTE requirements given in EPA Method 204.

We also proposed that owners or operators submit electronic copies of required compliance reports (at 40 CFR 63.366(b) and (c)), performance test reports (at 40 CFR 63.366(f)), and performance evaluation reports (at 40 CFR 63.366(g)) through the EPA's CDX using CEDRI, and we proposed two narrow circumstances in which owners or operators may, within five business days of the reporting deadline, seek extensions of that deadline if they are prevented from reporting by conditions outside of their control. We proposed at 40 CFR 63.366(h) that an extension may be warranted due to outages of the EPA's CDX or CEDRI that precludes an owner or operator from accessing the system and submitting required reports. We also proposed at 40 CFR 63.366(i) that an extension may be warranted due to a *force majeure* event, such as an act of nature, act of war or terrorism, or equipment failure or safety hazards beyond the control of the facility.

Finally, we proposed to reinstate title V permitting requirements for all area source facilities, and we proposed compliance mechanisms for owners and operators of combined emission streams. We also proposed revisions to clarify text or correct typographical errors, grammatical errors, and cross-reference errors.

2. How did the other amendments for the Commercial Sterilization Facilities source category change since proposal?

We are finalizing a requirement for owners and operators to use EtO CEMS to demonstrate compliance. In addition, for affected sources with a percent emission reduction standard, we are finalizing a requirement for source owners or operators to obtain and record hourly average ppbvd of EtO concentration, dscfm of flow rate, and weight differential in pounds of EtO used, to calculate and record each day of operation—where any operation less values obtained during periods of SSM constitute a day of operation—and the emission limit(s) based on the 30-operating day rolling sum of EtO entering the control system(s), as determined using values from the current operating day and the previous 29 operating days. However, owners and operators of facilities where EtO use is less than 100 lb/year will have the option to demonstrate compliance through annual performance testing and parametric monitoring. We are not including requirements for fenceline or ambient air monitoring in this final rule. For EtO CEMS, based on comments received during the proposed rulemaking, we are finalizing a requirement for quarterly reporting, as well as a minimum data availability of 90 percent. For performance testing, we are finalizing the incorporation of additional test methods. Based on comments received during the proposed rulemaking, we are also retaining currently approved test methods that we proposed to remove, and we are not finalizing a requirement to conduct SCV inlet testing. For performance test duration, based on comments received during the proposed rulemaking, we are not finalizing a requirement for 24-hour test runs. Instead, owners and operators may continue to conduct 1-hour test runs for ARVs, CEVs, room air emissions, or any combination thereof. For emission streams that contain an SCV, we are finalizing a requirement for owners and operators to include a representative test period as part of their test protocol, which is subject to approval from the delegated authority. Based on comments received during the proposed rulemaking, we are finalizing numerous revisions to the proposed requirements for parametric monitoring. Furthermore, based on comments received during the proposed

rulemaking, we are not finalizing a requirement for owners and operators that are required to comply with EPA Method 204 to conduct daily inspections of all applicable NDOs. Instead, we a finalizing a requirement for owners and operators to demonstrate continuous compliance with EPA Method 204 through the use of either outlet volumetric flow rate monitors or differential pressure monitors.

We are not finalizing a requirement for all area source facilities to obtain a title V operating permit. In addition, based on comments received during the proposed rulemaking, we are finalizing revised compliance mechanisms for combined emission streams. We are also finalizing an option for owners and operators to demonstrate compliance with a site-wide emission limitation, as opposed to demonstrating compliance for each individual and combined emission stream.

3. What key comments did we receive on the other amendments for the Commercial Sterilization Facilities source category and what are our responses?

Comment: We received extensive comment on our proposal to allow either the use of EtO CEMS or annual performance testing with parametric monitoring for demonstrating compliance with emission standards. Some commenters stated that EtO CEMS should be the only mechanism allowed for demonstrating compliance, as it will yield more real-time data that will allow for potential issues to be identified and resolved more quickly. Other commenters stated that EtO CEMS are a relatively new technology and that the available supply, reliability in industrial facilities, and maintenance support for EtO CEMS is questionable. Commenters also expressed concerns with parametric monitoring and pointed to our requirements for CEMS in other rules, as well as the fact that EtO CEMS are used in a number of sterilization facilities.

Response: In the majority of instances, parametric monitoring is used to good effect as an ongoing means of ensuring that control devices continue to get necessary emission reductions. However, given the nature of EtO, in which small amounts can have large risk impacts, parametric monitoring alone will not be sensitive enough to detect very small fluctuations. In addition, many facilities in this source category are controlling their EtO emissions using systems that contain one or more control devices, each with their own parametric monitoring requirements. While this has proven to be effective in reducing EtO emissions, it can lead to multiple, simultaneous parameter collection and processing, increasing system complexity and increasing the time necessary for diagnosis and correction of control device or process problems.

Therefore, the EPA is finalizing a requirement to only use CEMS for demonstrating compliance. However, facilities where EtO use is less than 100 lb/year will still have the option to use CEMS or performance testing and parametric monitoring to demonstrate compliance. This is because risk remains at acceptable levels for these facilities even when considering uncontrolled emissions. In addition, these facilities tend to have relatively simple control systems. Although EtO CEMS is a relatively new technology in this industry, it has been proven as a highly effective method for demonstrating compliance. While the use of these CEMS systems for low-level measurements of EtO is relatively new, they are in use in this sector; because of this, we find it technically feasible to require their use more broadly. Additionally, the EtO instruments used as part of these CEMS are readily available and although the low-level detection levels are recent, they have been demonstrated in the field.

Comment: We received extensive comments on our decision to not include fenceline or ambient air monitoring as part of the proposed rulemaking. Some commenters were supportive of this exclusion, stating that this source category is comprised of enclosed facilities with defined emission points (*e.g.,* windows, doors, ventilation exhaust) and that PTE is sufficient to ensure the containment of emissions. Other commenters were opposed to this exclusion, stating that fenceline and ambient air monitoring are necessary in order to ensure that commercial sterilization facilities are complying with the rule requirements, as well as to provide important information about emissions, exposure, and the efficacy of control equipment to nearby communities, regulatory agencies, and workers. The commenters pointed to other source categories where we have either required fenceline monitoring (*i.e.,* petroleum refineries) or proposed it (*i.e.,* the Synthetic Organic Chemical Manufacturing Industry and the Polymers and Resins industry).

Response: We acknowledge that many commenters expressed their strong support for fenceline monitoring requirements as part of this rule. As a general matter, fenceline monitoring is considered a particularly useful compliance monitoring approach if it is infeasible to enclose an emission source(s). This is the case for source categories where we have either required or proposed fenceline monitoring, such as refineries, because facilities within these source categories cover a wide variety of emission sources where PTE is not feasible. At such sources, it is frequently impossible to rapidly detect and remedy a leak or other unauthorized release without the use of fenceline monitoring.

By contrast, as discussed in section IV.B.3.c, PTE in accordance with EPA Method 204 has been demonstrated to be feasible for commercial sterilization facilities. As part of the PTE requirements the EPA is finalizing in this rule, the EPA is also requiring monitoring of either the volumetric flow rate from each outlet or differential pressure in order to ensure that the PTE is operating effectively on a continuous basis. Furthermore, as discussed above, we are requiring EtO CEMS at facilities where EtO use is at least 100 lb/year, which includes most facilities within the source category. The data from these CEMS will help to ensure that commercial sterilization facilities are complying with the rule requirements, and the data will be made available to the public, providing important information about emissions, exposure, and the efficacy of control equipment to nearby communities, regulatory agencies, and workers. As noted above, the physical configuration of commercial sterilizer facilities can also make the implementation of fenceline monitoring challenging at these sources. For these reasons, the EPA is not finalizing fenceline monitoring requirements as part of this rule.

Comment: We received extensive comments on our proposed requirement that EtO CEMS data be reported on a daily basis. Some commenters were supportive, stating that daily reporting provides assurance to the public that emission control devices are working as designed. Other commenters were opposed, stating that facilities need sufficient time to conduct QA/QC to verify the accuracy and reliability of the data and that reporting inaccurate data due to insufficient QA/QC would undermine public confidence of the CEMS monitoring and potentially adversely impact the medical supply chain if there is undue public concern. One commenter questioned whether there is a precedent for daily reporting, and another was unaware of any other NESHAP that requires daily reporting for CEMS. Several commenters stated that quarterly or semi-annual reporting is sufficient and more consistent with other NESHAPs.

Response: We agree with the commenters' concern that daily reporting of CEMS data is not appropriate. Sufficient time is needed so that the proper QA/QC procedures can be conducted to verify the accuracy and reliability of the data. Therefore, we are finalizing a requirement that CEMS data be reported quarterly, which is consistent with other NESHAPs that regulate pollutants of significant concern, as well as at least one sterilization facility that uses CEMS to demonstrate compliance with local requirements.

Comment: One commenter stated we did not address CEMS downtime and how downtime will be assessed or impact reporting. In addition, two commenters stated that there should be allowances or an exemption from sampling during periods of non-operation (*e.g.,* power outages, plant shutdowns).

Response: Our general policy is to require source owners and operators to have working monitoring while the emissions-producing process is operating and to identify those periods where monitoring is not working while the emissions-producing process is operating, as well as to quickly correct monitoring issues so that such periods are minimized. Recognizing that EtO CEMS are a newer technology that may pose challenges to users who may be unfamiliar with instrument characteristics, the rule will provide a period of data unavailability for up to ten percent of process operating time for EtO CEMS in operation before requiring additional corrective activity by owners or operators. Such an allowance, referred to as a minimum data availability requirement, has been used to good effect for other types of CEMS as they were introduced. As familiarity with those CEMS increased, so did their minimum data availability requirements; the EPA expects this pattern to continue for EtO CEMS such that in the future, the minimum data availability requirement for EtO CEMS will be replaced by the agency's general policy. Until then, the rule will have a minimum data availability for EtO CEMS of ninety percent. This means that EtO emissions data must be collected over at least ninety percent of the process operating time in order to avoid non-compliance and potential penalties. Data availability will be determined by assessment of the ratio of periods of valid EtO CEMS values to process operation periods, where valid EtO CEMS values occur when a minimum of 4 equally spaced values occur over an hour of process operation. Periods associated with normal quality assurance activities, such as daily calibrations, do not count as periods of data unavailability, however, periods of out-of-control monitor operation or when the EtO CEMS is unable to provide quality-assured data, such as those periods associated with monitor or data acquisition and handling system failure, do count as periods of data unavailability. Note that source owners or operators are to record EtO CEMS values during all periods of operation, include SSM, to the extent that the values are available. Source owners or operators will need to keep records of periods of process operation, EtO CEMS availability, and EtO CEMS unavailability; cause and duration of EtO CEMS unavailability; and of activity taken to correct and prevent future periods of EtO CEMS unavailability. Moreover, owners or operators will be required to provide immediate notice of failure to meet the data availability of 90 percent, as well as root cause analysis of periods of EtO CEMS monitor unavailability and specific corrective actions—along with schedule and enumerated expenditures—planned to address EtO CEMS unavailability.

Comment: Several commenters stated that the requirement to measure SCV inlets can create significant safety hazards. Two commenters stated that EtO concentrations in abatement system inlets coming from SCVs can reach several hundred thousand ppm. The commenters noted that these concentrations exceed the lower explosion limit of 30,000 ppm, thereby posing a significant explosion risk. Commenters noted that this situation could also expose workers to EtO levels above the Immediately Dangerous to Life or Health limit set by the U.S. Occupational Safety and Health Administration (OSHA), resulting in hazardous working conditions. Several commenters stated that we should retain the option to determine emission reduction using mass balance calculations and pounds of EtO injected into the sterilization chamber to ensure safe testing practices.

Response: We agree with the commenters' concerns regarding the safety risks associated with testing the SCV inlet. Therefore, we are removing this requirement for SCVs from the final rule. Owners and operators must instead determine the mass of EtO emissions from the SCV by measuring the daily change in weight of the EtO drums that are used to charge the sterilization chamber.

Comment: Several commenters were opposed to our proposed requirement for each performance test run to be conducted over a 24 hour period for facilities where EtO use is at least 10 tpy, stating that this requirement is difficult, infeasible, and of limited value. The commenters stated that there are a limited number of testing companies with both the experience to conduct performance tests of this length, as well as the personnel to remain at facilities during these long performance test periods. The commenters stated that multiple companies will be in demand for these limited services and that scheduling these performance tests so that the medical supply chain is not adversely impacted will be difficult. In general, the commenters agreed that a performance test run longer than one hour is necessary but were divided on what constitutes a representative period, with one commenter stating that eight to 10 hours is representative, and another stating that six to 12 hours is representative. Several commenters stated the performance test duration should be determined by the facility and accompanied with a justification of how normal operations are captured over this duration. One commenter stated that ARV and room air emissions are continuous in nature and that one-hour performance test runs are sufficient for these sources. The commenter also stated the CEV operations are started and completed within an hour and, therefore, one-hour performance test runs are appropriate for these sources as well. Finally, one commenter suggested that each performance test run for facilities where EtO use is less than 10 tpy should be longer than one hour.

Response: As discussed earlier, we are finalizing a requirement to only use EtO CEMS for demonstrating compliance. In addition, owners or operators of affected sources subject to a percent emission reduction standard will obtain and record EtO concentration in ppbvd, flow rate in dscfm, and daily EtO use in pounds; determine daily amounts of EtO entering and exiting control systems; use those daily amounts to calculate and record 30-operating day rolling sums; and calculate emission limits and determine compliance based on those rolling sums. However, facilities where EtO use is less than 100 lb/year will still have the option to use CEMS or performance testing and parametric monitoring to demonstrate compliance. Therefore, our proposal for each performance test run to be conducted over a 24-hour period for facilities where EtO use is at least 10 tpy is no longer applies and is not included in the final rule. For facilities where EtO use is less than 100 lb/year, we agree that a one-hour performance test period for

ARVs and room air emissions is appropriate, as these operations are continuous in nature, with minimal variations in emissions. We also agree that a one-hour performance test period is appropriate for CEVs, as these operations are typically started and concluded in less than one hour. For SCVs, the emissions profile can vary significantly depending on the number of chambers at a facility and how the emissions are staggered. Therefore, we are finalizing a requirement for owners and operators to include a representative performance test period for SCVs, along with a justification, in their stack test protocol, so that the delegated authorities can review and approve or deny the protocol as appropriate.

Comment: We received comments on continuous compliance requirements for verifying EPA Method 204. Several commenters contended that continuously verifying the direction of airflow through daily inspections of each NDO presents significant safety risks and are redundant or impractical. They noted that NDOs may be located at ceiling levels (such as a makeup air unit) in processing areas or in other hard to reach areas where EtO concentrations may require the use of specialized protective equipment. One commenter stated that streamers are not practical, may not be observable, and often get stuck or wrapped around objects. Another commenter noted that smoke testing in EtO facilities is discouraged due to safety concerns, as any indication of fire in an EtO facility is highly problematic, and seeing smoke within the facility should not be routine. Finally, two commenters questioned the value of daily NDO inspections when other relevant parameters are being continuously monitored.

One commenter recommended the use of differential pressure monitoring to verify EPA Method 204, accompanied by a data recording system to demonstrate continuous compliance. Other commenters were opposed to any continuous compliance requirements for verifying EPA Method 204, stating that they would be burdensome, expensive, and difficult to maintain. Two commenters stated that we should change the criteria for demonstrating continuous compliance with EPA Method 204 from ''maintained above 0.007 inches of water'' to ''at least 0.007 inches of water'' to align to the Method 204 definition of facial velocity equivalence.

Response: We agree with the commenters' concerns regarding the safety and practical aspects of daily NDO inspections. Therefore, we are not including this requirement in the final rule. In order to ensure that emissions are not leaving through uncontrolled spaces, it is critical to demonstrate continuous compliance with EPA Method 204. In the absence of daily NDO inspections, differential pressure monitoring and outlet volumetric flow rate monitoring are viable options for verifying the continuous flow of air into a control device, and both of these options were included in the proposed rulemaking. Therefore, we are finalizing a requirement for owners and operators to demonstrate continuous compliance with EPA Method 204 either through outlet volumetric flow rate monitoring or through differential pressure monitoring. We also agree with commenters that, if differential pressure monitoring is used, the pressure differential should be maintained at or above 0.007 inch of water in order to demonstrate continuous compliance, as this is what is required in EPA Method 204.

Comment: We received extensive comments on our proposed requirement for all area source facilities within the source category to obtain a title V operating permit. Several commenters were supportive, citing the serious health concerns of EtO. The commenters stated that facilities with title V operating permits tend to receive more oversight and that this, along with increased community engagement, will ensure that these facilities are complying with the rule requirements. Other commenters were opposed, stating the current and proposed NESHAP included substantial compliance, parametric monitoring, recordkeeping, and reporting obligations. One commenter stated that subjecting area source EtO commercial sterilizers to the title V permitting program requires additional regulatory fees; burdensome permitting, recordkeeping and reporting requirements; increased administrative costs; as well as Clean Air Act citizen suits. Two commenters suggested that the proposed requirements could be incorporated into a State minor source permit without the additional burden of title V permitting, and that title V permits should apply only to major sources. Multiple commenters also indicated that the four-factor balancing test still weighs in favor of continued exclusion of area source facilities within this source category from title V permitting requirements.

With respect to the first factor (*i.e.,* whether title V would result in significant improvements to the compliance requirements, including monitoring, recordkeeping, and reporting that are proposed for the area source category), several commenters stated that requiring title V operating permits would not provide significant improvements to compliance requirements. Two commenters agreed with our 2005 analysis that the NESHAP requirements applicable to area sources already subjected them to continuous monitoring and assessment, reporting, and certification of compliance status on a semiannual basis, which was similar to what was required by title V. Commenters stated that the proposed rule addressed increased transparency and further strengthened monitoring, recordkeeping, and reporting requirements, including developing a new performance specification and associated QA procedures for CEMS capable of detecting EtO at very low levels. One commenter stated that we recognized that modern NESHAPs have sufficient parametric monitoring. The commenter also stated that the only gain that we identified that was not already satisfied was the public comment period for title V permitting; however, the commenter noted that many facilities may need construction permits to come into compliance with the updated requirements, during which many States have an option to hold a public comment period and a public meeting(s) for changes that may be of interest to the community. The commenter noted that, as part of this rulemaking process, the EPA held numerous public meetings for local communities regarding specific facilities and additional public outreach meetings for transparency. This commenter stated these outreach efforts and the potential construction permitting actions will eliminate the need to have the title V public comment period. Three commenters stated that one of the primary purposes of the title V program was to clarify in a single document the various and complex regulations that applied to a facility in order to improve compliance. Two commenters stated that we agreed that EtO sterilizers were still subject only to a single NESHAP. Three commenters stated the benefit of requiring a title V permit to house all applicable regulations into a single document would not apply to those area sources and was not needed, and one commenter added that area sources should be exempt from title V on that basis alone. One commenter stated that, in response to a comment on our 2005 proposed rule, we also indicated that NESHAP provisions independently required schedules of compliance, provided inspection and entry

authority, and established emissions limitations and standards that were enforceable regardless of title V permitting. This commenter noted the proposed rule asserted that the compliance benefits of title V were greater today than in 2005 and so the benefits would be greater, but the commenter argued that we made these statements without providing supporting analysis.

With respect to the second factor (*i.e.,* whether title V permitting would impose significant burdens on the area source category and whether the burdens would be aggravated by any difficulty in obtaining assistance from permitting authorities), several commenters noted that requiring area sources to obtain a title V permit would pose significant burdens on sterilization facilities, with one commenter stating that it would pose significant burden ''within the time frame being proposed.'' [68] Additionally, the commenter stated the State permitting agencies may be overly burdened in issuing title V permits at a facility with such low emissions. Several commenters stated that the proposed title V permitting requirement for area sources would be a significant burden for small businesses, as these permits required businesses to prepare significant amounts of paperwork, negotiate compliance with the permitting authority, and subject their operations and permit application to public comment or petitions that would potentially delay operations and create additional regulatory burdens that, per OMB analysis, may be biased against small businesses. One commenter noted that small businesses in this industry had no experience with title V permitting and that obtaining these permits would require additional resources. The commenter stated that we ignored the significant cost of uncertainty that title V permitting introduced to small business planning. The commenter explained that rather than hiring an engineer to determine how a facility could meet the requirements, a small business would have to engage in a process with multiple partners, develop supporting material that may or may not be sufficient in the eyes of the regulatory authority, and prepare a public relations strategy in anticipation of community opposition to their operations, and that this investment must be made without the certainty of an outcome that will allow continued operation. One commenter noted that many Small Business Environmental Assistance Programs are precluded from assisting with title V permitees and, as such, this rule could strip small businesses of the assistance mandated under CAA section 507. One commenter stated that our justification seemed premised on an expectation of noncompliance, although clarified that we had not alleged that small commercial sterilizers have a history of noncompliance. The commenter noted that recent controversies around EtO facilities had centered around large facilities owned by large businesses. The commenter indicated it was not clear how title V permitting of area sources would create additional incentives for compliance or give State enforcement authorities the resources and expertise they would not otherwise have to enforce this NESHAP. One commenter stated the addition of title V permitting for area sources formalized community involvement in the authorization of area source commercial sterilizers, and that this level of community review was unnecessary and overly burdensome. Another commenter noted that the public already had access to commercial sterilizer locations, emissions, and current standards to which they were subject via our website and regulations, as well as our community outreach to advise the public of the hazards of EtO.

With respect to the third factor (*i.e.,* whether the costs of title V permitting for area sources would be justified taking into consideration any potential gains in compliance likely to occur for such sources), two commenters stated there would be no justification for imposing the burden of title V permitting. One commenter stated that we could have separated the cost estimate for the 86 area sources in order to provide more accurate numbers. Additionally, the commenter stated that the 2019 cost estimates were not accurate, as the new rules would require facilities to change not only their equipment, but also their calculation methods, monitoring, and testing. The commenter stated that those costs needed to be considered in a title V cost analysis. Three commenters stated that our cost estimate for obtaining a title V permit underestimated the cost of this requirement and that we should not add to the burdens for area sources. One commenter stated that the time and cost of getting a title V permit did not correlate to the potential gains and that we provided no supporting data for our conclusion that the average costs associated with title V ($67,211 for the first year, as calculated in 2019) will likely be less for area sources. This commenter suggested that our cost determination did not align with the proposed rule, which said ''the rule amendments proposed provide for a greater degree of complexity and requirements to achieve and demonstrate compliance for area sources.'' One commenter noted that we stated that the burden was not insignificant, but justified the costs because it represented a small portion of the anticipated costs related to the amendments of the proposed rule. One commenter stated that the analysis on title V applicability did not ask how the burden compared to the cost of complying [with] some other measure, but that the question was whether the potential compliance benefits outweighed the steep costs, the answer to which we seemed to concede was ''no.''

With respect to the fourth factor (*i.e.,* whether adequate oversight by State and local permitting authorities could achieve high compliance with the NESHAP requirements without relying on title V permitting), one commenter stated that CAA sections 112, 113, and 114 required implementation and enforcement programs to be conducted by the EPA or delegated to the proper State authority and a small business assistance program to assist area sources exempted from title V with compliance. The commenter noted that States and the EPA routinely conducted voluntary compliance assistance outreach and education programs. The commenter noted that the EPA's review of State-provided empirical data demonstrated that area sources were adequately compliant with their requirements without title V permitting. The commenter stated that the proposed rule is silent on whether permitting authorities could effectively implement NESHAPs without title V, and that the EPA alluded to its 2019 ICR, implying that the responses thereto supported the EPA's title V decision, but the EPA never identified specific data or explained how it would support any of EPA's cursory statements. The commenter concluded that there was no more difficulty enforcing the single NESHAP for area sources now versus in 2005, when EPA unequivocally determined title V would provide no benefits to its ability to enforce CAA regulations in tandem with its State and local partners. The commenter stated that requiring title V now would only make enforcement more difficult, as State agencies would be flooded with

[68] Commenter provided the following statement: ''Requiring areas sources to obtain a title V permit would pose significant burdens on sterilization facilities especially within the time frame being proposed.'' (see Docket Item No. EPA–HQ–OAR–2019–0178–0632, Attachment 2, page 20).

title V applications that would require time and State funds to implement and could potentially shift attention away from major source compliance in a way that would compromise (and not improve) implementation of any final NESHAP program. Another commenter stated there was already sufficient oversight by State and local permitting authorities, as well as subpart O requirements. One commenter stated that, as a State regulatory agency, they had the ability to adequately ensure compliance with the proposed standard for facilities within their jurisdiction regardless of whether the facility is subject to title V permitting. Another commenter stated the proposed removal of the title V permitting exemption for area sources meant a significant number of small operations would be required to obtain title V permits for the first time, and as many of these area sources were subject to a limited set of applicable requirements and permits, there was little apparent benefit from the consolidation of these requirements within a title V permit. One commenter stated that the EPA failed to discuss whether there was a history of noncompliance with the EtO Commercial Sterilization NESHAP, which indicated that that there are few potential gains from the increased burdens. Finally, one commenter stated that State operating permits (*e.g.,* Synthetic Minor or Federally Enforceable State Operating Permits) are abundant and adequate to deal with these GACT sources without the added expense, complication, and delays associated with title V permitting.

Response: We agree with commenters that the four-factor balancing test continues to weigh in favor of exempting area source facilities from title V permitting. In particular, we agree with commenters that one of the primary benefits of the title V program is to clarify, in a single document, the various and complex regulations that apply to a facility in order to improve compliance, and that this benefit is not realized in this case because commercial sterilization facilities are subject to only one NESHAP (Subpart O). In addition, we agree with commenters that, in light of the robust monitoring, recordkeeping and reporting requirements in the final rule, a title V permit would likely not add any substantial monitoring, recordkeeping and reporting requirements. We further note that, even in the absence of title V permitting requirements, this final rule will ensure transparency around the emissions from these facilities by requiring that EtO CEMS data be reported on a quarterly basis, and this data will be made available to the public.

In summary, the benefits of requiring title V permitting for area source facilities are not outweighed by the concerns. For the reasons stated above, we agree with commenters that the four-factor balancing test continues to weigh in favor of exempting area source facilities from title V permitting on the basis that title V is unnecessarily burdensome. Therefore, we are not finalizing title V permitting requirements for area source facilities.

Comment: One commenter suggested that we require only a single combined performance test for the outlet point and that the most stringent applicable standard (*i.e.,* the control level required for the SCV) should be applied. Two commenters stated that our affected source proposal is unnecessarily complicated. One commenter stated that where control equipment has a single inlet and outlet, the facility should not be required to test individual source inlets or outlets. The commenter also stated that it is logical that point sources routed to the same emission control system should be defined as a single unit. The commenter stated it is important to set emission limits that reflect this reality and test methods that allow for combined system testing at the outlet of the system. The commenter also stated that the proposed language implies that the SCV, CEV, and ARV must be tested separately, which is challenging given the complexity in design of existing duct work and access to inlets. The commenter stated that testing the combined inlet to the APCD would be the safest, most accurate, and most cost-effective method for determining compliance for facilities with combined emissions. Another commenter stated that applying the most restrictive removal efficiency standard when different sources are combined is impractical.

Response: The EPA is finalizing approaches that will provide facilities with flexibility in terms of how they choose to demonstrate compliance with the standards for instances where emission streams are combined prior to entering a control system. Facilities can determine compliance via one of two options:

- *Option 1:* Determine the mass of EtO entering the control device at a point after the emission streams are combined, and apply the most stringent emission reduction standard that the component streams are subject to.
- *Option 2:* Determine the mass of EtO entering the control device at points before the emission streams are combined, and apply the emission reduction standards that the component streams are subject to.

Option 1 is consistent with what was proposed, and Option 2 has been added in order to provide more flexibility for facilities in terms of how they chose to demonstrate compliance. As an example, suppose an area source facility uses at least 30 tpy but less than 60 tpy, and the facility chooses to control all of its ARVs and CEVs with one control system. The emission reduction standards that apply to the ARVs and CEVs are 99.9% and 99%, respectively. In this example, suppose the mass of EtO emissions from the ARVs is 4 lb, and the mass of EtO emissions from the CEVs is 1 lb, meaning that the mass of EtO emissions from the combined stream is 5 lb. Under Option 1, the facility would need to apply an emission reduction of 99.9% to the combined stream, resulting in an emission limit of 0.005 lb. Under Option 2, the facility would apply an emission reduction of 99.9% to the ARV stream and an emission reduction of 99% to the CEV stream, resulting in an emission limit of 0.014 lb. When an affected source is subject to a relatively high emission reduction standard, it can be difficult to demonstrate compliance with that standard when the concentration of pollutants going into the control device is low. By combining emission streams and increasing the concentration of pollutants in the air stream, it is easier to demonstrate compliance.

Comment: One commenter recommended the creation of the option for a site-wide emission limitation. This limitation could take the form of either overall removal efficiency, or a total mass rate per hour. Another commenter suggested a site-wide emission limitation based upon EtO usage and end-state emissions and identified as precedent an Illinois construction permit containing monthly and annual mass emissions caps. The commenter also suggested a compliance option by emission reduction or emission rate standards and identified as precedent Illinois legislation requiring 99.9 percent emission reduction at each exhaust point or limitation of EtO emissions to 0.2 ppm.

Response: We agree with the creation of an option for a site-wide emission limitation and have included this in the final rulemaking. Specifically, we are finalizing two options for determining compliance on a site-wide basis:

- *Option 1:* Determine the mass of EtO being used at the facility and apply the SCV emission reduction standard, which is the most stringent emission

reduction standard that any emission stream at the facility is subject to.

• *Option 2:* Determine the mass of EtO being emitted from each affected source, and apply the emission reduction standards that each affected source is subject to. For SCVs, the mass of EtO may be determined by measuring how much is used and then applying a facility-specific factor that accounts for EtO entering the control systems from other affected sources.

We disagree with the suggestion to set an emissions cap, as the amount of EtO that a facility will use in a given month is unknown.

4. What is the rationale for our final approach and final decisions for the other amendments for the Commercial Sterilization Facilities source category?

We are not finalizing a requirement for all area sources facilities to obtain a title V operating permit, and we are not including requirements for fenceline or ambient air monitoring as part of this final rule. Based on the comments received during the proposed rulemaking, we are requiring EtO CEMS for facilities where EtO use is at least 100 lb/year, and we are finalizing a requirement for EtO CEMS data to be reported quarterly. We are not finalizing a requirement for owners and operators to conduct SCV inlet testing, and we are not finalizing a requirement for each performance test run to be conducted over a 24-hour period. Lastly, we are finalizing revised compliance mechanisms for combined emission streams, as well as the option for facilities to demonstrate compliance with a site-wide emission limit, as opposed to having to demonstrate compliance for each individual and combined emission stream. See section IV.F.3 of this preamble for further discussion.

In a few instances, we received comments that led to additional minor editorial corrections and technical clarifications being made in the final rule, and our rationale for these corrections and technical clarifications can be found in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* available in the docket for this rulemaking.

V. Summary of Cost, Environmental, and Economic Impacts and Additional Analyses Conducted

A. What are the affected facilities?

As part of the proposed rulemaking, we estimated that there were 86 existing commercial sterilization facilities and two planned facilities. However, based on comments received on the proposed rulemaking, we understand that one of the existing facilities has closed. In addition, the commenters identified three existing commercial sterilization facilities that were unknown during the proposed rulemaking. However, it should be noted that EtO use at the three facilities that were previously unknown is very small (*i.e.,* less than 1 tpy). A complete list of the known 88 Commercial Sterilization Facilities that are affected by this rulemaking is available in Appendix 1 of the document, *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2024 Risk and Technology Review Final Rule,* which is available in the docket for this rulemaking.

B. What are the air quality impacts?

At the current level of control prior to the amendments being finalized in this action, the EPA estimates that EtO emissions were approximately 23 tpy (actuals) and 160 tpy (allowables) from commercial sterilization facilities. At the level of control required by the amendments being finalized in this action, which includes standards for previously unregulated sources and amendments to all sources where standards were already in place, we estimated EtO emissions reductions of 21 tpy (actuals) and 150 tpy (allowables) for the source category.

C. What are the cost impacts?

The total capital investment cost of the final amendments and standards is estimated to be approximately $313 million in 2021 dollars. We estimate total annual costs of the final amendments to be approximately $74 million.

The present value (PV) of the estimated compliance costs over the 20-year timeframe from 2025 to 2044 for the final rule is $773 million in 2021 dollars, discounted at a 7 percent rate. The equivalent annualized value (EAV) of the costs is $88 million, using a 7 percent discount rate. Using a 3 percent discount rate, the PV and EAV of the costs from 2025 to 2044 are estimated to be $932 million and $63 million, respectively.

The nationwide costs of the different amendments being finalized in this action are presented in table 2 of this preamble. As described in this preamble, we are finalizing standards for previously unregulated sources, as well as amendments for sources where standards were already in place. Many of the emissions capture and control technologies that are needed to comply with the final rule will impact multiple sources at once, and those costs form the basis of our impact estimates. These costs are presented in table 2 of this preamble. There are 90 facilities (including the 88 existing facilities and the two planned facilities) affected by the amendments, and the number of facilities associated with each of the specific costs is indicated in table 2. The facility list was developed using methods described in section II.C of the proposal preamble (88 FR 22790, April 13, 2023). A complete list of known commercial sterilization facilities is available in Appendix 1 of the document, *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2024 Risk and Technology Review Final Rule,* which is available in the docket for this rulemaking.

D. What are the economic impacts?

The economic impact analysis is designed to inform decision makers about the potential economic consequences of the compliance costs outlined in section V.C of this preamble. The EPA performed a screening analysis that compared compliance costs to revenues at the ultimate parent company level (several companies own more than one affected facility). This is known as the cost-to-revenue or cost-to-sales test, or the ''sales test.'' The use of a sales test for estimating small business impacts for a rulemaking is consistent with EPA guidance on compliance with the Regulatory Flexibility Act (RFA) and is consistent with guidance published by the U.S. Small Business Administration's Office of Advocacy that suggests that cost as a percentage of total revenues is a metric for evaluating cost increases on small entities in relation to increases on large entities.

There are 88 existing commercial sterilization facilities and 2 planned commercial sterilization facilities, owned by 50 parent companies, affected by the final amendments. Of the parent companies, 22 companies, or 44 percent, are small entities based on the U.S. Small Business Administration's table of size standards. Next, we determined the magnitude of the costs of the amendments being finalized in this action for each entity and then calculated a cost-to-sales ratio for each entity by comparing estimated costs to the annual revenues of each parent company. We then assessed whether there would be potential for a significant impact on small entities based on the cost-to-sales ratios. For all entities, the average cost-to-sales ratio is approximately 8 percent; the median cost-to-sales ratio is 0.2 percent; and the

maximum cost-to-sales ratio is approximately 69 percent. For large firms, the average cost-to-sales ratio is approximately 0.2 percent; the median cost-to-sales ratio is 0.03 percent; and the maximum cost-to-sales ratio is 1.3 percent. This rule has potentially significant impacts on small entities. For small firms, the average cost-to-sales ratio is approximately 18 percent, the median cost-to-sales ratio is 4.7 percent, and the maximum cost-to-sales ratio is 69 percent. There are 13 small entities (59 percent of all affected small entities) with estimated cost-to-sales ratios of 3 percent or greater. See the Regulatory Impact Analysis for further detail on the cost estimates, small entity impact analysis, and a discussion of potential market and economic impacts.

The EtO sterilization industry is an integral part of the supply chain for many medical devices and capacity constraints have been reported. Based on the data we analyzed, we expect that the largest impacts of this rule are limited to a handful of the companies that play a key role in the availability of certain medical devices, and several of them are already in the planning stage for additional controls.

Some companies involved in medical device sterilization have installed, or are already planning for installation of, additional emissions controls. The controls necessary to meet the requirements of this final rule include PTEs and gas/solid reactors, along with (in some cases) alterations to facility design to ensure adequate capture of EtO emissions. Such controls rely on existing technologies that are commercially available from manufacturers and are already well established in this industry. In addition, a few companies have constructed, or are in the process of constructing, new facilities with state-of-the-art design and control installations to ensure full capture and control of EtO emissions. These early actions by industry demonstrate the feasibility of implementing the requirements in this final rule.

Over the last several years, the industry has demonstrated the capability to install controls on multiple facilities simultaneously without interfering with medical supply chains. For example, three companies re-designed their Illinois and Georgia facilities to comply with the PTE requirements of EPA Method 204, as well as installed emission controls at these facilities during overlapping timeframes from May 2019 through August 2020 without disruption to the medical supply chain. As discussed in section III.G of this preamble, we have reviewed the time that it has taken for these projects to be completed, from submission of the initial permit application to installation of the continuous compliance mechanisms. Based on this review, we found that the process of bringing a facility into compliance with the PTE requirements of EPA Method 204, as well as installing and verifying additional emission controls, takes approximately a year from permit submission to project completion.

The EPA has evaluated available information about the state of control installations at existing commercial sterilization facilities. Of the 88 existing facilities, seven appear have already met the emission standards and will not need to install additional emission controls. Another 55 facilities appear to only need additional abatement devices. We expect that 28 facilities still need to meet the PTE requirements of EPA Method 204 and install additional abatement devices. Table 22 presents the apparent compliance status with the final rule for each relevant emission source and facility EtO use combination, based on controls that are currently in place.

TABLE 22—APPARENT COMPLIANCE STATUS WITH FINAL RULE AND COMPLIANCE TIMEFRAMES

Emission source	Facility EtO use	Number of facilities with this affected source	Number of facilities appearing to achieve final standard [1]	Compliance timeframe
SCV	At least 30 tpy	38	19	Two years.
	At least 10 but less than 30 tpy.	9	9	Two years.
	At least 1 but less than 10 tpy.	18	16	Two years.
	Less than 1 tpy	23	22	Three years.
ARV	At least 30 tpy	36	12	Two years.
	At least 10 but less than 30 tpy.	5	5	Three years.
	At least 1 but less than 10 tpy.	10	7	Three years.
	Less than 1 tpy	4	2	Three years.
CEVs at major source facilities	N/A	0	N/A	Three years.
CEVs at area source facilities	At least 60 tpy	25	12	Two years.
	Less than 60 tpy	15	8	Three years.
Group 1 room air emissions at major sources	N/A	0	N/A	Three years.
Group 1 room air emissions at area sources	At least 40 tpy	36	16	Two years.
	Less than 40 tpy	38	7	Three years.
Group 2 room air emissions at major sources	N/A	1	0	Three years.
Group 2 room air emissions at area sources	At least 20 tpy	44	17	Two years.
	At least 4 but less than 20 tpy.	13	1	Two years.
	Less than 4 tpy	27	27	Three years.

[1] The phrase ''appearing to achieve'' is used (as opposed to ''achieving'') to account for uncertainties in the data. A notable example is the SCVs where, for a given facility, the emission reduction on the first evacuation may not high enough to ensure that the standard is being met across all evacuations. Another uncertainty is the fraction of EtO going to each emission stream. In some instances, there is facility-specific information available, and in others, there is no information available and default fractions are applied as a result.

E. What are the benefits?

The EPA did not monetize the benefits from the estimated emission reductions of HAP associated with this final action. The EPA currently does not have sufficient methods to monetize benefits associated with HAP, HAP reductions, and risk reductions for this rulemaking. However, we estimate that the final rule amendments would reduce EtO emissions by 21 tons per year and expect that these reductions will lower the risk of adverse health effects, including cancer, for individuals in communities near commercial sterilization facilities. For example, the estimated cancer incidence due to emissions from the source category would be reduced from 0.9 to between 0.1 to 0.2, or from 1 cancer case every 1.1 years to 1 cancer case every 5 to 10 years.

F. What analysis of environmental justice did we conduct?

Consistent with applicable executive orders and EPA policy, the EPA has carefully analyzed the environmental justice implications of the benefits associated with the reductions in EtO emissions as a result of this final rule. The EPA conducted this analysis for the purpose of providing the public with as full as possible an understanding of the potential impacts of this final action. The EPA believes that analyses like this can inform the public's understanding, place EPA's action in context, and help, identify and illustrate the extent of potential burdens and protections.

As part of understanding the impacts of this source category and of this final rule, we examined the potential for the 88 facilities that were assessed to pose concerns to communities with EJ concerns both in the baseline *i.e.,* under the current standards) standards considered in this final rule.

To examine the potential for EJ concerns in the pre-control baseline, we conducted two baseline demographic analyses, a proximity analysis and a risk-based analysis. The baseline proximity demographic analysis is an assessment of individual demographic groups in the total population living within 10 kilometers (km) and 50 km of the facilities. In this preamble, we focus on the 10 km radius for the health risk assessment and for the demographic analysis because it encompasses all the facility MIR locations and captures 100 percent of the population with risks greater than 100-in-1 million. The results of the proximity analysis for populations living within 50 km are included in the technical report included in the docket for this final rule for the public's understanding.

The baseline risk-based demographic analysis is an assessment of risks to individual demographic groups in the population living within the 10 km and 50 km radii around the facilities prior to the implementation of any controls finalized by this action (''baseline''). Again, in this preamble, we present for the public's understanding the results for populations living within 10 km of facilities. Results for populations living within 50 km are included in the technical report included in the docket for this final rule.

Overall, the results of the proximity demographic analysis (see first three columns of table 23) indicate that the percent of the population living within 10 km of the 88 facilities that is Hispanic or Latino is substantially higher than the national average (36 percent versus 19 percent), driven largely by the seven facilities in Puerto Rico. The baseline proximity analysis indicates that the proportion of other demographic groups living within 10 km of commercial sterilizers is closer to the national average. The baseline risk-based demographic analysis (see ''baseline'' column in tables 23 to 25), which presents information for individuals that are expected to have higher cancer risks (greater than or equal to 1-in-1 million, greater than or equal to 50-in-1 million, and greater than 100-in-1 million), suggests that the African American, Hispanic or Latino, below the poverty level, over 25 and without a high school diploma, and linguistically isolated demographic groups are also disproportionally represented at the higher risk levels.

The post-control risk-based demographic analysis presents information on current health risks and how the standards considered in this final regulatory action would affect the distribution of these risks across the populations and communities identified in the baseline. The CAA section 112(d)(2), (3), and (5) post-control scenario is shown in tables 23 to 25 and the residual risk post-control options are shown in tables 26 to 28. The post-control options show a substantial reduction in the number of individuals at each risk level, as well as a significant reduction in the proportion of African Americans that experience higher risk levels from facilities in this source category. We project that a majority of the individuals that would remain at risk after implementation of the final standards are Hispanic or Latino, driven largely by the facilities in Puerto Rico.

These three distinct but complementary analyses indicate the potential for EJ concerns associated with this source category in the baseline, as well as the substantial anticipated benefits these final standards will have in reducing EtO emissions and associated health risks for all of the affected public, including people living in communities with EJ concerns. Those benefits include that no individual is expected to be exposed to inhalation cancer risk levels above 100-in-1 million due to emissions from this source category after implementation of all the CAA standards finalized in this action.

The methodology and detailed results of the demographic analysis are presented in a technical report, *Analysis of Demographic Factors for Populations Living Near Ethylene Oxide Commercial Sterilization and Fumigation Operations,* available in the docket for this action, but a synopsis is provided below. We also received comments on the demographic analysis. Those comments and our specific responses can be found in the document, *Summary of Public Comments and Responses for the 2024 Risk and Technology Review for Commercial Sterilization Facilities,* available in the docket for this rulemaking.

1. Demographics

The first three columns of tables 23, 24, and 25 of this document show the total population, population percentages, and population count for each demographic group for the nationwide population and the total population living within 10 km of EtO sterilization facilities. A total of 17.3 million people live within 10 km of the 88 facilities that were assessed. The results of the proximity demographic analysis indicate that the percent of the population that is Hispanic or Latino is substantially higher than the national average (36 percent versus 19 percent), driven by the seven facilities in Puerto Rico, where an average of 99 percent of the 658,000 people living within 10 km of the facilities in PR are Hispanic or Latino. The percent of the population that is ''Other and multiracial'' (11 percent) is higher than the national average (8 percent). The percent of people living below the poverty level (15 percent) and those over the age of 25 without a high school diploma (16 percent) are higher than the national averages (13 percent and 12 percent, respectively). The percent of people living in linguistic isolation [69] is double

[69] Linguistic Isolation is defined in the U.S. Census Bureau's American Community Survey as ''a household in which all members age 14 years and over speak a non-English language and also

Continued

the national average (10 percent versus 5 percent). We note that this estimate of linguistic isolation is largely driven by the facilities in Puerto Rico, where an average of 67 percent of the population is in linguistic isolation in comparison to the national average.

In summary, the baseline proximity analysis indicates that the percent of Hispanic or Latino populations living near commercial sterilizers (within 10 km) is higher than what would be expected based on the national average distribution. This is largely driven by the seven facilities located in Puerto Rico where, on average, the population of 658,000 people living within 10 km of these seven facilities is 99 percent Hispanic or Latino. In addition, the population around the facilities in Puerto Rico has 67 percent living in linguistic isolation, 45 percent living below the poverty level, and 24 percent over 25 without a high school diploma.

2. Baseline Risk-Based Demographics

The baseline risk-based demographic analysis results are shown in the ''baseline'' column of tables 23, 24, and 25. This analysis presented information on the populations living within 10 km of the facilities with estimated actual cancer risks greater than or equal to 1-in-1 million (table 23), greater than or equal to 50-in-1 million (table 24), and greater than 100-in-1 million (table 25). The risk analysis indicated that emissions from the source category, prior to the reductions we are finalizing, expose a total of 5.3 million people to a cancer risk greater than or equal to 1-in-1 million around 75 facilities, 124,000 people to a cancer risk greater than or equal to 50-in-1 million around 38 facilities, and 19,000 people to a cancer risk greater than 100-in-1 million around 16 facilities. The demographics of the baseline population with estimated cancer risks greater than or equal to 1-in-1 million are very similar to the total population within 10 km. Specifically, the percent of the population that is Hispanic or Latino is more than two times larger than the national average (39 percent versus 19 percent), the percent below the poverty level is above national average (16 percent versus 13 percent), the percent over 25 without a high school diploma is above the national average (18 percent versus 12 percent), and the percent linguistic isolation is two times the national average (11 percent versus 5 percent).

In contrast, the smaller populations with baseline cancer risk greater than or equal to 50-in-1 million (124,000 people), and greater than 100-in-1 million (19,000 people) are predominantly made up of African Americans (43 and 31 percent versus 12 percent nationally), and have a higher percentage of the population below the poverty level (22 and 25 percent versus 13 percent nationally). For this same group, the percent over 25 without a high school diploma is above the national average (17 and 18 percent versus 12 percent), and linguistic isolation is above the national average (9 and 16 percent versus 5 percent). This shows that risks tend to be higher both where more African American residents reside, and where poverty is higher than in the rest of the area within 10 km. It should be noted that the higher percentage African American population with baseline cancer risk greater than or equal to 50-in-1 million is driven largely by seven facilities located in or near communities that have African American populations that are between two and eight times the national average. The higher percentage African American population with baseline cancer risk greater than 100-in-1 million is driven largely by three facilities that are located in communities where the proportion of African American residents is between 2.5 and 8 times the national average. The population with higher baseline cancer risks living within 10 km of the facilities consists of a substantially smaller percentage of Hispanic or Latino (22 and 26 percent) than the total population living within 10 km (36 percent Hispanic or Latino) and is above the national average (19 percent).

In summary, the baseline risk-based demographic analysis, which presents information on those specific locations that are expected to have higher cancer risks, suggests that African Americans, those living below poverty, and those living in linguistic isolation are disproportionally represented where risk is highest. The population with risks greater than 100-in-1 million living within 10 km of a commercial sterilizer has a proportion of African Americans (31 percent), those living below poverty (25 percent) and those living in linguistic isolation (16 percent) that is more than twice as large as the respective national average.

3. Risks Across Demographics Anticipated After Standards Under CAA Sections 112(d)(2), 112(d)(3), and 112(d)(5)

This analysis presented information on the populations living within 10 km of the facilities with estimated cancer risks greater than or equal to 1-in-1 million (table 23), greater than or equal to 50-in-1 million (table 24), and greater than 100-in-1 million (table 25) after implementation of standards that we are finalizing under CAA sections 112(d)(2), (3), and (5). The results of our analysis of risk-based demographics considering standards under CAA sections 112(d)(2), (3), and (5) are shown in the last column of tables 23, 24, and 25 titled ''Baseline and CAA Section 112(d)(2), (3), and (5).'' In this analysis we evaluated how the final CAA sections 112(d)(2), (3), and (5) emission reductions in this final regulatory action affect the distribution of risks identified in the baseline. This enables us to characterize the post-control risks and to illustrate for the public's understanding whether this part of the final action affects, creates or mitigates potential EJ concerns as compared to the baseline.

The risk analysis indicated that the emissions from the source category, after implementation of the standards (resulting in emissions reductions) that we are finalizing under CAA sections 112(d)(2), (3), and (5), reduces the number of people living within 10 km of a facility and with a cancer risk greater than or equal to 1-in-1 million from 5.3 million people around 75 facilities to 3.2 million people around 70 facilities, reduces the number of people living within 10 km of a facility and with a cancer risk greater than or equal to 50-in-1 million from 124,000 people around 38 facilities to 23,000 people around 23 facilities, and reduces the number of people living within 10 km of a facility and with a cancer risk greater than 100-in-1 million from 19,000 people around 16 facilities to 3,900 people around 13 facilities.

The demographics of the population with estimated cancer risks greater than or equal to 1-in-1 million considering the standards we are finalizing under CAA sections 112(d)(2), (3), and (5) are very similar to both the total population within 10 km and to the baseline population with risks greater than or equal to 1-in-1 million. Specifically, the percent of the population that is Hispanic or Latino is twice the national average (38 percent versus 19 percent), the percent below the poverty level is above national average (16 percent versus 13 percent), the percent over 25 without a high school diploma is above the national average (18 percent versus 12 percent), and the percent linguistic isolation is two times the national average (11 percent versus 5 percent).

After implementation of the standards that we are finalizing under CAA sections 112(d)(2), (3), and (5), the percentage and number of African Americans at cancer risks greater than

speak English less than ''very well'' (have difficulty with English).''

or equal to 50-in-1 million and greater than 100-in-1 million is significantly reduced. For example, African Americans exposed to risks greater than 100-in-1 million went from 31 percent or 5,900 people in the baseline to 6 percent or 220 people after implementation of the final CAA section 112(d)(2), 112(d)(3), and 112(d)(5) emissions reductions. It should be noted that while the number of Hispanic or Latino people with risks greater than 100-in-1 million was reduced from 4,900 to 2,600 people, the percentage of the remaining population at >100-in-1 million risk that is Hispanic or Latino went up from 26 percent in the baseline to 68 percent after the final CAA section 112(d)(2), 112(d)(3), and 112(d)(5) emissions reductions. However,. Similarly, the number of people below the poverty level or linguistically isolated with a cancer risk >100-in-1 million decreased significantly; however, the percentage of the remaining population at risk post-emission controls that are in these demographics went up from the baseline. For example, the proportion of the population with risks greater than 100-in-1 million that were below the poverty level was much higher than the baseline (38 percent versus 25 percent), but the number of people was reduced from 4,700 people to 560 people.

In summary, implementation of the final CAA sections 112(d)(2), (3), and (5) standards would significantly reduce the number of people in all demographic groups that are exposed to risks greater than or equal to 1-in-1 million, greater than and equal to 50-in-1 million, and greater than 100-in-1 million. Specifically, the percent of the population that is African American who are at a cancer risk greater than or equal to 50-in-1 million and greater than 100-in-1 million was reduced from 43 percent in the baseline to about 13 percent after the CAA section 112(d)(2), 112(d)(3), and 112(d)(5) controls. The percentage of Hispanic or Latino people increased as the higher risk facilities in Puerto Rico make-up an increasing portion of the remaining populations with higher cancer risks.

TABLE 23—COMPARISON AT BASELINE AND CAA SECTION 112(d)(2), (3), AND (5) POST-CONTROL OF DEMOGRAPHICS OF POPULATIONS WITH CANCER RISK GREATER THAN OR EQUAL TO 1-IN-1 MILLION LIVING WITHIN 10 KM OF FACILITIES THAT WERE ASSESSED

Demographic group	Nationwide	Total population living within 10 km of EtO facilities	Cancer risk ≥ 1-in-1 million	
			Baseline	Post-control
Total Population	328M	17.3M	5.3M	3.2M
Number of Facilities	.....	88	75	70
Race and Ethnicity by Percent [Number of People]				
White	60 percent [197M]	40 percent [6.9M]	40 percent [2.1M]	40 percent [1.3M]
African American	12 percent [40M]	13 percent [2.3M]	15 percent [770K]	16 percent [520K]
Native American	0.7 percent [2M]	0.3 percent [51K]	0.3 percent [17K]	0.3 percent [9K]
Hispanic or Latino (includes white and nonwhite)	19 percent [62M]	36 percent [6.2M]	39 percent [2.1M]	38 percent [1.2M]
Other and Multiracial	8 percent [27M]	11 percent [1.9M]	7 percent [350K]	6 percent [190K]
Income by Percent [Number of People]				
Below Poverty Level	13 percent [44M]	15 percent [2.5M]	16 percent [840K]	16 percent [520K]
Above Poverty Level	87 percent [284M]	85 percent [14.8M]	84 percent [4.5M]	84 percent [2.7M]
Education by Percent [Number of People]				
Over 25 and without a High School Diploma	12 percent [40M]	16 percent [2.7M]	18 percent [960K]	18 percent [590K]
Over 25 and with a High School Diploma	88 percent [288M]	84percent [14.6M]	82 percent [4.3M]	82 percent [2.7M]
Linguistically Isolated by Percent [Number of People]				
Linguistically Isolated	5 percent [18M]	10 percent [1.8M]	11 percent [570K]	11 percent [360K]

Notes:

- Nationwide population and demographic percentages are based on the Census Bureau's (Census) 2015–2019 American Community Survey (ACS) 5-year block group averages. Total population count within 10 km is based on 2010 Decennial Census block population.
- To avoid double counting, the "Hispanic or Latino" category is treated as a distinct demographic category. A person who identifies as Hispanic or Latino is counted as Hispanic or Latino, regardless of race.
- The number of facilities represents facilities with a cancer MIR above level indicated. When the MIR was located at a user assigned receptor at an individual residence and not at a census block centroid, we were unable to estimate population and demographics for that facility.
- The sum of individual populations with a demographic category may not add up to total due to rounding.

TABLE 24—COMPARISON AT BASELINE AND CAA SECTION 112(d)(2), (3), AND (5) POST-CONTROL OF DEMOGRAPHICS OF POPULATIONS WITH CANCER RISK GREATER THAN OR EQUAL TO 50-IN-1 MILLION LIVING WITHIN 10 KM OF FACILITIES THAT WERE ASSESSED

Demographic group	Nationwide	Total population living within 10 km of EtO facilities	Cancer risk ≥ 50-in-1 million	
			Baseline	Post-control
Total Population	328M	17.3M	124,000	23,000
Number of Facilities	.....	88	38	23
Race and Ethnicity by Percent [Number of People]				
White	60 percent [197M]	40 percent [6.9M]	31 percent [39K]	30 percent [7K]
African American	12 percent [40M]	13 percent [2.3M]	43 percent [54K]	13 percent [2.9K]
Native American	0.7 percent [2M]	0.3 percent [51K]	0.1 percent [190]	0.1 percent [<100]
Hispanic or Latino (includes white and nonwhite)	19 percent [62M]	36 percent [6.2M]	22 percent [27K]	56 percent [13K]
Other and Multiracial	8 percent [27M]	11 percent [1.9M]	3 percent [3.9K]	2 percent [400]
Income by Percent [Number of People]				
Below Poverty Level	13 percent [44M]	15 percent [2.5M]	22 percent [28K]	29 percent [6.6K]
Above Poverty Level	87 percent [284M]	85 percent [14.8M]	78 percent [96K]	71 percent [17K]
Education by Percent [Number of People]				
Over 25 and without a High School Diploma	12 percent [40M]	16 percent [2.7M]	17 percent [21K]	21 percent [5K]
Over 25 and with a High School Diploma	88 percent [288M]	84 percent [14.6M]	83 percent [103K]	79 percent [18K]
Linguistically Isolated by Percent [Number of People]				
Linguistically Isolated	5 percent [18M]	10 percent [1.8M]	9 percent [11K]	30 percent [6.9K]

Notes:

• Nationwide population and demographic percentages are based on Census' 2015–2019 ACS 5-year block group averages. Total population count within 10 km is based on 2010 Decennial Census block population.

• To avoid double counting, the ''Hispanic or Latino'' category is treated as a distinct demographic category. A person who identifies as Hispanic or Latino is counted as Hispanic or Latino, regardless of race.

• The number of facilities represents facilities with a cancer MIR above level indicated. When the MIR was located at a user assigned receptor at an individual residence and not at a census block centroid, we were unable to estimate population and demographics for that facility.

• The sum of individual populations with a demographic category may not add up to total due to rounding.

• To account for the uncertainty of demographics estimates in smaller populations, any population values of 100 persons or less have been shown simply as ''<100.''

TABLE 25—COMPARISON AT BASELINE AND CAA SECTION 112(d)(2), (3), AND (5) POST-CONTROL OF DEMOGRAPHICS OF POPULATIONS WITH CANCER RISK GREATER THAN 100-IN-1 MILLION LIVING WITHIN 10 KM OF FACILITIES THAT WERE ASSESSED

Demographic group	Nationwide	Total population living within 10 km of EtO facilities	Cancer risk > 100-in-1 million	
			Baseline	Post-control
Total Population	328M	17.3M	19,000	3,900
Number of Facilities	.....	88	16	13
Race and Ethnicity by Percent [Number of People]				
White	60 percent [197M]	40 percent [6.9M]	40 percent [7.7K]	25 percent [1K]
African American	12 percent [40M]	13 percent [3M]	31 percent [5.9K]	6 percent [200]
Native American	0.7 percent [2M]	0.3 percent [51K]	0.1 percent [<100]	0 percent [0]

TABLE 25—COMPARISON AT BASELINE AND CAA SECTION 112(d)(2), (3), AND (5) POST-CONTROL OF DEMOGRAPHICS OF POPULATIONS WITH CANCER RISK GREATER THAN 100-IN-1 MILLION LIVING WITHIN 10 KM OF FACILITIES THAT WERE ASSESSED—Continued

Demographic group	Nationwide	Total population living within 10 km of EtO facilities	Cancer risk > 100-in-1 million	
			Baseline	Post-control
Hispanic or Latino (includes white and nonwhite)	19 percent [62M]	36 percent [6.2M]	26 percent [4.9K]	68 percent [2.6K]
Other and Multiracial	8 percent [27M]	11 percent [1.9M]	3 percent [500]	1 percent [<100]
Income by Percent [Number of People]				
Below Poverty Level	13 percent [44M]	15 percent [2.5M]	25 percent [4.7K]	38 percent [1.4K]
Above Poverty Level	87 percent [284M]	85 percent [14.8M]	75 percent [14K]	62 percent [2.4K]
Education by Percent [Number of People]				
Over 25 and without a High School Diploma	12 percent [40M]	16 percent [2.7M]	18 percent [3.5K]	22 percent [900]
Over 25 and with a High School Diploma	88 percent [288M]	84 percent [14.6M]	82 percent [16K]	78 percent [3K]
Linguistically Isolated by Percent [Number of People]				
Linguistically Isolated	5 percent [18M]	10 percent [1.8M]	16 percent [3K]	44 percent [1.7K]

Notes:
- Nationwide population and demographic percentages are based on Census' 2015–2019 ACS 5-year block group averages. Total population count within 10 km is based on 2010 Decennial Census block population.
- To avoid double counting, the ''Hispanic or Latino'' category is treated as a distinct demographic category. A person who identifies as Hispanic or Latino is counted as Hispanic or Latino, regardless of race.
- The number of facilities represents facilities with a cancer MIR above level indicated. When the MIR was located at a user assigned receptor at an individual residence and not at a census block centroid, we were unable to estimate population and demographics for that facility.
- The sum of individual populations with a demographic category may not add up to total due to rounding.
- To account for the uncertainty of demographics estimates in smaller populations, any population values of 100 persons or less have been shown simply as ''<100.''

4. Demographics of Affected Populations Anticipated After Implementation of Residual Risk Standards (Post-Control)

This analysis presented information on the populations living within 10 km of the facilities with estimated cancer risks greater than or equal to 1-in-1 million (table 26), greater than or equal to 50-in-1 million (table 27), and greater than 100-in-1 million (table 28) after implementation of the standards being finalized under CAA section 112(f)(2) as described in section IV.C of this preamble. The demographic results for the risks after implementation of the residual risk-based controls are in the column titled ''Residual Risk Standards.'' These standards will be implemented in addition to the CAA section 112(d)(2), (3), and (5) standards and are anticipated to result in additional post-control emissions reductions. Therefore, in this analysis, we evaluated how all of the final standards and emission reductions described in this action affect the reduction and distribution of risks. This enables us to characterize the post-control risks and to understand whether the final action affects, creates or mitigates potential EJ concerns as compared to the baseline.

The risk analysis indicated that the number of people exposed to risks greater than or equal to 1-in-1 million within 10 km of a facility (table 26) is reduced from 3.2 million people after implementation of the CAA section 112(d)(2), (3), and (5) controls to approximately 700,000 people after implementation of the residual risk standards. This represents a significant reduction (about 80 percent reduction) in the size of the population facing this level of risk after implementation of the residual risk standards being finalized, when compared to the population facing this level of risk after implementation of just the CAA section 112(d)(2), (3), and (5) controls. The people with a cancer risk greater than or equal to 1-in-1 million are located around 67 facilities after implementation of the residual risk standard-based controls.

The demographics of the post-control population living within 10 km of a facility and with an estimated cancer risks greater than or equal to 1-in-1 million after implementation of the residual risk standards and resulting controls (table 26) are very similar to the CAA section 112(d)(2), (3), and (5) post-control population with risks greater than or equal to 1-in-1 million. Specifically, the percent of the population that is Hispanic or Latino is nearly twice the national average (34 percent versus 19 percent), the percent below poverty is above national average (15 percent versus 13 percent), the percent over 25 without a high school diploma is above the national average (15 percent versus 12 percent), and the percent linguistic isolation is almost two times the national average (11 percent versus 5 percent).

The risk analysis indicated that the number of people living within 10 km of a facility and exposed to risks greater than or equal to 50-in-1 million (table 27) is reduced from 23,000 people after implementation of the CAA section

112(d)(2), (3), and (5)-based controls to 170 people after implementation of the residual risk-based controls. This represents a 99 percent reduction in the size of the populations at risk. The people living within 10 km of a facility and with a cancer risk greater than or equal to 50-in-1 million after implementation of the final rule are located around 11 facilities.

The demographic breakdown of the much smaller post-control population living within 10 km of a facility and with estimated cancer risks greater than or equal to 50-in-1 million for the residual risk controls (table 27) is significantly different from the population after implementation of the CAA section 112(d)(2), (3), and (5) controls. Specifically for the 170 individuals still at greater than or equal to 50-in-1 million risk, the percent of the population that is Hispanic or Latino is significantly higher at 76 percent for the residual risk controls. This higher percentage is driven by two facilities in Puerto Rico, for which the population is over 99 percent Hispanic or Latino. However, the number of Hispanic or Latino people with risks greater than or equal to 50-in-1 million was reduced by about 99 percent from 13,000 people to 130 people after anticipated implementation of the residual risk standard-based controls. Similarly, the percentage of the population that is below the poverty level or linguistically isolated went up from the CAA section 112(d)(2), (3), and (5) post-control population, but the number of people in each demographic decreased significantly.

The risk analysis indicated that the number of people living within 10 km of a facility and exposed to risks greater than 100-in-1 million (table 28) is reduced from 3,900 people after implementation of the CAA section 112(d)(2), (3), and (5)-based controls to zero people for residual risk-based controls. After implementation of the residual risk standards, there are no facilities or people with risks greater than 100-in-1 million. Therefore, there are no greater than 100-in-1 million risk populations or demographics to discuss.

In summary, as shown in the residual risk post-control risk-based demographic analysis, the standards being finalized will reduce the number of people and facilities expected to have cancer risks greater than or equal to 1-in-1 million, greater than or equal to 50-in-1 million, and greater than 100-in-1 million significantly. Under residual risk-based controls, the number of Hispanic or Latino people that are exposed to risks greater than or equal to 1-in-1 million is reduced by 80 percent, the number of Hispanic or Latino people that are exposed to risks greater than or equal to 50-in-1 million is reduced by 99 percent, and the number of Hispanic or Latino people that are exposed to risks greater than 100-in-1 million is reduced by 100 percent. We note that, primarily driven by the higher risk facilities in Puerto Rico, the percentage of population that is Hispanic or Latino, below the poverty level, over 25 without a high school diploma, or in linguistic isolation increases as the cancer risk increases from greater than or equal to 1-in-1 million to greater than 50-in-1 million. Under residual risk-based controls, there are no facilities or people with risks greater than 100-in-1 million.

TABLE 26—COMPARISON OF DEMOGRAPHICS FOR POPULATIONS WITH CANCER RISK GREATER THAN OR EQUAL TO 1-IN-1 MILLION LIVING WITHIN 10 KM OF STERILIZER FACILITIES AFTER IMPLEMENTATION OF VARIOUS COMPONENTS OF THE FINAL STANDARDS

Demographic group	Nationwide	Cancer risk ≥1-in-1 million	
		Post-control CAA section 112(d)(2), (3), and (5) standards	Residual risk standards (CAA section 112(f)(2))
Total Population	328M	3.2M	700K
Number of Facilities with Pop. Above Cancer Level	.....	70	67
Race and Ethnicity by Percent [Number of People]			
White	60 percent [197M]	40 percent [1.3M]	40 percent [280K]
African American	12 percent [40M]	16 percent [520K]	18 percent [130K]
Native American	0.7 percent [2M]	0.3 percent [9K]	0.2 percent [2.2K]
Hispanic or Latino (includes white and nonwhite)	19 percent [62M]	38 percent [1.2M]	34 percent [240K]
Other and Multiracial	8 percent [27M]	6 percent [190K]	8 percent [53K]
Income by Percent [Number of People]			
Below Poverty Level	13 percent [44M]	16 percent [520K]	15 percent [100K]
Above Poverty Level	87 percent [284M]	84 percent [7M]	85 percent [600K]
Education by Percent [Number of People]			
> 25 w/o a HS Diploma	12 percent [40M]	18 percent [590K]	15 percent [110K]
> 25 w/HS Diploma	88 percent [288M]	82 percent [2.7M]	85 percent [590K]

TABLE 26—COMPARISON OF DEMOGRAPHICS FOR POPULATIONS WITH CANCER RISK GREATER THAN OR EQUAL TO 1-IN-1 MILLION LIVING WITHIN 10 KM OF STERILIZER FACILITIES AFTER IMPLEMENTATION OF VARIOUS COMPONENTS OF THE FINAL STANDARDS—Continued

Demographic group	Nationwide	Cancer risk ≥1-in-1 million	
		Post-control CAA section 112(d)(2), (3), and (5) standards	Residual risk standards (CAA section 112(f)(2))
Linguistically Isolated by Percent [Number of People]			
Linguistically Isolated	5 percent [18M]	11 percent [360K]	11 percent [80K]

Notes:
• Nationwide population and demographic percentages are based on Census' 2015–2019 ACS 5-year block group averages. Total population count within 10 km is based on 2010 Decennial Census block population.
• To avoid double counting, the ''Hispanic or Latino'' category is treated as a distinct demographic category. A person who identifies as Hispanic or Latino is counted as Hispanic or Latino, regardless of race.
• The number of facilities represents facilities with a cancer MIR above level indicated. When the MIR was located at a user assigned receptor at an individual residence and not at a census block centroid, we were unable to estimate population and demographics for that facility.
• The sum of individual populations with a demographic category may not add up to total due to rounding.

TABLE 27—COMPARISON OF DEMOGRAPHICS FOR POPULATIONS WITH CANCER RISK GREATER THAN OR EQUAL TO 50-IN-1 MILLION LIVING WITHIN 10 KM OF STERILIZER FACILITIES AFTER IMPLEMENTATION OF VARIOUS COMPONENTS OF THE FINAL RULE

Demographic group	Nationwide	Cancer risk ≥50-in-1 million post-control	
		CAA section 112(d)(2), (3), and (5) standards	Residual risk standards (112(f)(2))
Total Population	328M	23,000	170
Number of Facilities with Pop. Above Cancer Level	.....	23	11
Race and Ethnicity by Percent [Number of People]			
White	60 percent [197M]	30 percent [7K]	12 percent [<100]
African American	12 percent [40M]	13 percent [2.9K]	11 percent [<100]
Native American	0.7 percent [2M]	0.1 percent [190]	0.3 percent [<100]
Hispanic or Latino (includes white and nonwhite)	19 percent [62M]	56 percent [13K]	76 percent [130]
Other and Multiracial	8 percent [27M]	2 percent [400]	0.4 percent [<100]
Income by Percent [Number of People]			
Below Poverty Level	13 percent [44M]	29 percent [6.6K]	30 percent [<100]
Above Poverty Level	87 percent [284M]	71 percent [17K]	70 percent [120]
Education by Percent [Number of People]			
>25 w/o a HS Diploma	12 percent [40M]	21 percent [5K]	31 percent [<100]
>25 w/HS Diploma	88 percent [288M]	79 percent [18K]	69 percent [120]
Linguistically Isolated by Percent [Number of People]			
Linguistically Isolated	5 percent [18M]	30 percent [6.9K]	47 percent [<100]

Notes:
• Nationwide population and demographic percentages are based on Census' 2015–2019 ACS 5-year block group averages. Total population count within 10 km is based on 2010 Decennial Census block population.
• To avoid double counting, the ''Hispanic or Latino'' category is treated as a distinct demographic category. A person who identifies as Hispanic or Latino is counted as Hispanic or Latino, regardless of race.

• The number of facilities represents facilities with a cancer MIR above level indicated. When the MIR was located at a user assigned receptor at an individual residence and not at a census block centroid, we were unable to estimate population and demographics for that facility.
• The sum of individual populations with a demographic category may not add up to total due to rounding.
• To account for the uncertainty of demographics estimates in smaller populations, any population values of 100 persons or less have been shown simply as ''<100''.

TABLE 28—COMPARISON OF DEMOGRAPHICS FOR POPULATIONS WITH CANCER RISK GREATER THAN 100-IN-1 MILLION LIVING WITHIN 10 KM OF STERILIZER FACILITIES AFTER IMPLEMENTATION OF VARIOUS COMPONENTS OF THE FINAL RULE

Demographic group	Nationwide	Cancer risk >100-in-1 million	
		CAA section 112(d)(2), (3), and (5) post-control	Residual risk controls
Total Population	328M	3,900	0
Number of Facilities with Pop. Above Cancer Level	.....	13	0
Race and Ethnicity by Percent [Number of People]			
White	60 percent [197M]	25 percent [1K]	.....
African American	12 percent [40M]	6 percent [200]	.....
Native American	0.7 percent [2M]	0 percent [0]	.....
Hispanic or Latino (includes white and nonwhite)	19 percent [62M]	68 percent [2.6K]	.....
Other and Multiracial	8 percent [27M]	1 percent [<100]	.....
Income by Percent [Number of People]			
Below Poverty Level	13 percent [44M]	38 percent [1.4K]	.....
Above Poverty Level	87 percent [284M]	62 percent [2.4K]	.....
Education by Percent [Number of People]			
>25 w/o a HS Diploma	12 percent [40M]	22 percent [900]	.....
>25 w/HS Diploma	88 percent [288M]	78 percent [3K]	.....
Linguistically Isolated by Percent [Number of People]			
Linguistically Isolated	5 percent [18M]	44 percent [1.7K]	.....

Notes:
• Nationwide population and demographic percentages are based on Census' 2015–2019 ACS 5-year block group averages. Total population count within 10 km is based on 2010 Decennial Census block population.
• To avoid double counting, the ''Hispanic or Latino'' category is treated as a distinct demographic category. A person who identifies as Hispanic or Latino is counted as Hispanic or Latino, regardless of race.
• The number of facilities represents facilities with a cancer MIR above level indicated. When the MIR was located at a user assigned receptor at an individual residence and not at a census block centroid, we were unable to estimate population and demographics for that facility.
• The sum of individual populations with a demographic category may not add up to total due to rounding.
• To account for the uncertainty of demographics estimates in smaller populations, any population values of 100 persons or less have been shown simply as ''<100''.

VI. Statutory and Executive Order Reviews

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

This action is a ''significant regulatory action'', as defined under section 3(f)(1) of Executive Order 12866, as amended by Executive Order 14094. Accordingly, the EPA submitted this action to the Office of Management and Budget (OMB) for Executive Order 12866 review. Documentation of any changes made in response to the Executive Order 12866 review is available in the docket. The EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis, *Regulatory Impact Analysis for the Final National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations,* is also available in the docket.

B. Paperwork Reduction Act (PRA)

The information collection activities in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 1666.12. You can find a copy of the ICR in the docket for this rulemaking, and it is briefly summarized here.

We are amending the reporting and recordkeeping requirements for several

emission sources at commercial sterilization facilities (*e.g.,* SCV, ARV, CEV, and room air emissions). The amendments also require electronic reporting, removes the SSM exemption, and imposes other revisions that affect reporting and recordkeeping. This information was be collected to assure compliance with 40 CFR part 63, subpart O.

Respondents/affected entities: Owners or operators of commercial sterilization facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart O).

Estimated number of respondents: 88 facilities.

Frequency of response: Quarterly, semiannual, or annual. Responses include notification of compliance status reports and semiannual compliance reports.

Total estimated burden: 34,351 hours (per year) for the responding facilities and 9,174 hours (per year) for the Agency. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $5,140,563 (per year), which includes $2,549,368 annualized capital and operation and maintenance costs for the responding facilities.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 603 of the RFA, the EPA prepared a final regulatory flexibility analysis (FRFA) that examines the impact of the rule on small entities along with regulatory alternatives that could minimize the impact. The complete FRFA is available for review in the docket and is summarized here.

1. Statement of Need and Rule Objectives

This industry is regulated by the EPA because pollutants emitted from EtO sterilization and fumigation facilities are considered to cause or contribute significantly to air pollution that may reasonably be anticipated to endanger public health. This action is being finalized to comply with CAA section 112 requirements, which direct the EPA to complete periodic reviews of NESHAPs following initial promulgation. The requirements are being finalized to address unacceptable health risks linked to emissions from subpart O facilities and to provide an ample margin of safety to protect public health.

The EPA is required under CAA section 112(d) to establish emission standards for each category or subcategory of major and area sources of HAPs listed for regulation in section 112(b). These standards are applicable to new or existing sources of HAPs and require the maximum degree of emission reduction. The EPA is required to review these standards set under CAA section 112 every eight years following their promulgation and revise them as necessary, taking into account any ''developments in practices, processes, or control technologies.'' This review is known as the technology review. It has been over 25 years since the initial NESHAP for this source category was promulgated in 1994 and roughly 15 years since the last technology review. As such, this final rule is overdue. This rule also establishes standards for currently unregulated sources of EtO emissions at subpart O facilities under CAA section 112(d), such as room air emissions. The decision in *Louisiana Environmental Action Network* v. *EPA, 955 F.3d 1088* (D.C. Cir. 2020) concluded that the EPA is required to address regulatory gaps (*i.e.,* ''gap-filling'') when conducting NESHAP reviews. Finally, the EPA determined that a risk review was warranted (despite not being required) due to the updated unit risk estimate associated with EtO, which is significantly higher than it was during the last review of this NESHAP in 2006. Therefore, the EPA is finalizing requirements under CAA section 112(f) to address unacceptable health risk attributed to emissions from subpart O facilities and to provide an ample margin of safety to protect public health.

2. Significant Issues Raised by the Public Comments in Response to the Initial Regulatory Flexibility Analysis (IRFA) and EPA Response

While the EPA did not receive any comments specifically in response to the IRFA, we did receive comments from the Office of Advocacy within the Small Business Administration (SBA), and a summary of the major comments and our responses is provided in the next section. The issues raised by SBA were also reflected in comments from small businesses and organizations with small business interests.

3. SBA Office of Advocacy Comments and EPA Response

The SBA's Office of Advocacy (hereafter referred to as ''Advocacy'') provided substantive comments on the April 2023 Proposal. Those comments made the following claims: (1) the proposed compliance period for existing sources (18 months) would disadvantage small business; (2) the proposed requirement for area source commercial sterilization facilities to obtain a title V permit would impose significant costs and uncertainty for small businesses; and (3) EPA should adopt the BMP alternatives for GACT at area source facilities. Based on those claims, Advocacy insisted that EPA reconsider these policies to reduce the impact on small entities and reduce the likelihood they will leave the market.

In response to Advocacy's comments, EPA agrees that the proposed compliance timeframe is too short and that more time is needed to comply with the rule. Therefore, as part of the final rulemaking, EPA is providing the maximum amount of time that is allowed under the CAA to comply with the emission standards, which is three years for standards that are promulgated pursuant to CAA section 112(d) and two years for standards that are promulgated pursuant to CAA section 112(f)(2). With respect to title V permitting, because of the lack of other Federal requirements under the CAA that commercial sterilization facilities are subject to, as well as the robust monitoring and reporting requirements of the final rule, the EPA is not finalizing a requirement for area source facilities to obtain a title V permit. In addition, with respect to GACT, emission standards were evaluated against the BMP on a source-by-source basis. In general, we are finalizing the emission standards for each source pursuant to CAA section 112(d)(5), with the exception of existing Group 2 room air emissions at areas source facilities, because they achieve higher emission reductions than the BMP. Further discussion is available in section IV.B.3.

More detailed responses to Advocacy's comments can be found in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Commercial Sterilization Facilities,* available in the docket for this rulemaking.

4. Estimate of the Number of Small Entities to Which the Final Rule Applies

For purposes of assessing the impacts of this rule on small entities, a small entity is defined as a small business in the commercial EtO sterilization

industry whose parent company has revenues or numbers of employees below the SBA Size Standards for the relevant NAICS code. We have identified 20 different NAICS codes within this source category. A complete list of those NAICS codes and SBA Size Standards is available in section 5.2 of the RIA. The rule contains provisions that will affect 22 small entities. These small entities are involved in sterilizing various types of medical devices and spices. In addition, at least 12 of these small entities are involved in sterilizing the types of medical devices discussed in section I.A.1 of this preamble.

5. Projected Reporting, Recordkeeping and Other Compliance Requirements of the Final Rule

Under the rule requirements, small entities will be required to comply with various emission standards, which may require the use of one or more new control devices. Small entities will also need to demonstrate compliance with the emission standards through the use of an EtO CEMS or through periodic performance testing and parametric monitoring. This rule includes reporting, recordkeeping, and other administrative requirements. Under the rule, the EPA estimates that approximately 13 small entities (60 percent of small entities) could incur total annual costs associated with the proposal that are at least three percent of their annual revenues. Considering the level of total annual costs relative to annual sales for these small entities, the EPA determined that there is potential for the requirements to have a 'Significant Impact on a Substantial Number of Small Entities'. See section 5.2 of the RIA for more information on the characterization of the impacts under the rule.

6. Steps Taken To Minimize Economic Impact to Small Entities

a. Small Business Advocacy Review Panel

As required by section 609(b) of the RFA, the EPA also convened a Small Business Advocacy Review (SBAR) Panel to obtain advice and recommendations from small entity representatives (SERs) that potentially would be subject to the rule's requirements. On November 25, 2020, the EPA's Small Business Advocacy Chairperson convened the Panel, which consisted of the Chairperson, the Director of the Sector Policies and Programs Division within the EPA's Office of Air Quality Planning and Standards, the Administrator of the Office of Information and Regulatory Affairs within OMB, and the Chief Counsel for Advocacy of the SBA.

Prior to convening the Panel, the EPA conducted outreach and solicited comments from the SERs. After the Panel was convened, the Panel provided additional information to the SERs and requested their input. In light of the SERs' comments, the Panel considered the regulatory flexibility issues and elements of the IRFA specified by RFA/Small Business Regulatory Enforcement and Fairness Act and developed the findings and discussion summarized in the SBAR report. The report was finalized on April 26, 2021, and transmitted to the EPA Administrator for consideration. A copy of the full SBAR Panel Report is available in the rulemaking docket.

b. Alternatives Considered

The SBAR Panel recommended several flexibilities relating to the format of the standards, room air emissions requirements, subcategorization, the compliance timeframe, the consideration of GACT standards, incentivizing lower EtO use, a compliance alternative for combined emission streams, proximity requirements, and the consideration of interactions with OSHA standards. The EPA is including some of these flexibilities as a part of the rule requirements.

As discussed in section VI.C.3, the EPA is providing the maximum amount of time that is allowed under the CAA to comply with the emission standards. In addition, as discussed in section IV.B.3.b, the EPA is not any finalizing any mass rate emission standards and is finalizing percent emission reduction standards in their place. Finally, as discussed in section IV.F.3, the EPA is finalizing compliance flexibilities for combined emission streams, as well as the option to demonstrate compliance with a site-wide emission limit, as opposed to having to demonstrate compliance with each individual or combined emission stream.

In addition, the EPA is preparing a Small Entity Compliance Guide to help small entities comply with this rule. The Small Entity Compliance Guide will be available on the same date as the date of publication of the final rule or as soon as possible after that date and will be available on the rule web page at: *https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities.*

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more 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.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

This action does not have Tribal implications as specified in Executive Order 13175. None of the commercial sterilization facilities that have been identified as being affected by this final action are owned or operated by Tribal governments or located within Tribal lands within a 10-mile radius. Thus, Executive Order 13175 does not apply to this action. We conducted an impact analysis using the latitude and longitude coordinates from the risk modeling input file to identify Tribal lands within a 10- and 50-mile radius of commercial sterilization facilities to determine potential air quality impacts on Tribes. Consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, although there were no Tribal lands located within a 10-mile radius of commercial sterilization facilities, the EPA offered consultation with all Tribes that were identified within a 50-mile radius of an affected facility, however, only one Tribal official requested consultation. Additional details regarding the consultation letter and distribution list can be found in the memorandum, *Commercial Sterilization Facilities RTR Consultation Letter,* which is available in the docket for this rulemaking. The EPA also participated on a phone call with the National Tribal Air Association on May 25, 2023, and presented an overview of the rulemaking.

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

Executive Order 13045 (62 FR 19885, April 23, 1997) directs Federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in Federal health

and safety standards and explain why the regulation is preferable to potentially effective and reasonable feasible alternatives. This action is subject to Executive Order 13045 because it is a 3(f)(1) significant regulatory action as defined by Executive Order 12866, and the EPA believes that the environmental health or safety risk addressed by this action has a disproportionate effect on children. The EPA's Policy on Children's Health also applies to this action. Accordingly, we have evaluated the environmental health or safety effects of EtO emissions and exposures on children. The protection offered by these standards may be especially important for children.

Because EtO is mutagenic (*i.e.,* it can damage DNA), children are expected to be more susceptible to its harmful effects. To take this into account, as part of the risk assessment in support of this rulemaking, the EPA followed its guidelines and applied age-dependent adjustment factors (ADAFs) for early lifestage exposures (from birth up to 16 years of age). With the ADAF applied to account for greater susceptibility of children, the adjusted EtO inhalation URE is $5 \times 10-3$ per $\mu g/m^3$. It should be noted that, because EtO is mutagenic, emission reductions in this preamble will be particularly beneficial to children. In addition, children are at increased risk if they live, play, or attend school in close proximity to a commercial sterilization facility, of which there are many cases noted by the public to be the case. For these reasons, there is both increased susceptibility and increased exposure for early lifestages as a result of EtO emissions from commercial sterilization facilities.

A total of 3.97 million children ages 0–17 live within 10km of commercial sterilization facilities. Due to baseline emissions from commercial sterilization facilities (prior to application of controls in this action), there are approximately 1.25 million children (0–17 years) with increased lifetime cancer risks of greater than or equal to 1-in-1 million, 30,000 with increased lifetime cancer risks greater than or equal to 50-in-1 million, and 4,300 with increased lifetime cancer risks greater than 100-in-1 million. After application of the controls in this action, lifetime cancer risks to children from commercial sterilization facility emissions decrease significantly to approximately 162,300 children with increased lifetime cancer risks of greater than or equal to 1-in-1 million, less than 100 with increased lifetime cancer risks of greater than or equal to 50-in-1 million, and none with increased lifetime cancer risks greater than 100-in-1 million. The methodology and detailed results of the demographic analysis are presented in a technical report, *Analysis of Demographic Factors for Populations Living Near Ethylene Oxide Commercial Sterilization and Fumigation Operations,* available in the docket for this action.

More detailed information on the evaluation of the scientific evidence and policy considerations pertaining to children, including an explanation for why the Administrator judges the standards to be requisite to protect public health, including the health of children, with an adequate margin of safety, in addition to the summaries of this action's health and risk assessments are contained in sections II.A and IV.C of this preamble and further documented in the risk report, *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2024 Risk and Technology Review Final Rule,* which is available in Docket ID No. EPA–HQ–OAR–2019–0178.

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

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The overall energy impact of this rule should be minimal for commercial sterilization facilities and their parent companies. EPA was unable to quantify the degree to which manufacturers will need to switch sites, so we cannot estimate potential energy impacts related to transportation. The EPA solicited comment on any potential impacts the proposed standards may have in relation to energy use for transportation but did not receive any comments that would help to quantify such impacts.

I. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This rulemaking involves technical standards. The EPA conducted searches for the standards through the Enhanced National Standards Systems Network Database managed by the American National Standards Institute (ANSI). We also contacted voluntary consensus standards (VCS) organizations and accessed and searched their databases. We conducted searches for EPA Methods 1, 1A, 2, 2A, 2C, 3A, 3B, and 4 of 40 CFR part 60, Appendix A, EPA Method 204 of 40 CFR part 51, Appendix M, and EPA Methods 301 and 320 in 40 CFR part 63, Appendix A. During the EPA's VCS search, if the title or abstract (if provided) of the VCS described technical sampling and analytical procedures that are similar to the EPA's reference method, the EPA reviewed it as a potential equivalent method.

The EPA incorporates by reference VCS ANSI/ASME PTC 19.10–1981 Part 10, ''Flue and Exhaust Gas Analyses,'' a method for quantitatively determining the gaseous constituents of exhausts resulting from stationary combustion and includes a description of the apparatus, and calculations used which are used in conjunction with Performance Test Codes to determine quantitatively, as an acceptable alternative to EPA Method 3B of appendix A to 40 CFR part 60 for the manual procedures only and not the instrumental procedures. The ANSI/ASME PTC 19.10–1981 Part 10 method incorporates both manual and instrumental methodologies for the determination of oxygen content. The manual method segment of the oxygen determination is performed through the absorption of oxygen. This method is available at the American National Standards Institute (ANSI), 1899 L Street NW, 11th floor, Washington, DC 20036 and the American Society of Mechanical Engineers (ASME), Three Park Avenue, New York, NY 10016–5990. See *https://www.ansi.org* and *https://www.asme.org.*

The EPA incorporates by reference VCS ASTM D6348–12 (Reapproved 2020), ''Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform (FTIR) Spectroscopy,'' as an acceptable alternative to EPA Method 320 of appendix A to 40 CFR part 63 with caveats requiring inclusion of selected annexes to the standard as mandatory. The ASTM D6348–12 (R2020) method is an extractive FTIR spectroscopy-based field test method and is used to quantify gas phase concentrations of multiple target compounds in emission streams from stationary sources. This field test method provides near real time analysis of extracted gas samples. In the September 22, 2008, NTTAA summary, ASTM D6348–03(2010) was determined equivalent to EPA Method 320 with caveats. ASTM D6348–12 (R2020) is a revised version of ASTM D6348–03(2010) and includes a new section on accepting the results from direct measurement of a certified spike gas cylinder, but still lacks the caveats we placed on the D6348–03(2010) version. We are finalizing that the test plan preparation and implementation in the Annexes to ASTM D 6348–12 (R2020), Sections Al through A8 are mandatory;

and in ASTM D6348–12 (R2020) Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (equation A5.5). We are finalizing that, in order for the test data to be acceptable for a compound, %R must be 70% ≤ R ≤ 130%. If the %R value does not meet this criterion for a target compound, the test data is not acceptable for that compound and the test must be repeated for that analyte (*i.e.,* the sampling and/or analytical procedure should be adjusted before a retest). The %R value for each compound must be reported in the test report, and all field measurements must be corrected with the calculated %R value for that compound by using the following equation:

$$Reported\ Results = \frac{Stack\ Concentration}{\%R} = 100$$

The ASTM D6348–12 (R2020) method is available at ASTM International, 1850 M Street NW, Suite 1030, Washington, DC 20036. See *https://www.astm.org/.*

ASTM D3695–88 is already approved for the locations in which it appears in the amendatory text.

While the EPA identified 12 other VCS as being potentially applicable, the Agency decided not to use them because these methods are impractical as alternatives due to lack of equivalency, documentation, validation data, and other important technical and policy considerations. The search and review results have been documented and are in the memorandum, *Voluntary Consensus Standard Results for National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review,* which is available in the docket for this rulemaking.

Under 40 CFR 63.7(f) and 40 CFR 63.8(f), subpart A—General Provisions, a source may apply to the EPA for permission to use alternative test methods or alternative monitoring requirements in place of any required testing methods, performance specifications, or procedures in the final rule or any amendments.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

The EPA believes that the human health or environmental conditions that exist prior to this action result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with EJ concerns. A total of 17.3 million people live within 10 km of the 88 facilities that were assessed. The percent of the population that is Hispanic or Latino is substantially higher than the national average (36 percent versus 19 percent), driven by the seven facilities in Puerto Rico, where an average of 99 percent of the 658,000 people living within 10 km of the facilities are Hispanic or Latino. The proportion of other demographic groups living within 10 km of commercial sterilizers is similar to the national average. The EPA also conducted a risk assessment of possible cancer risks and other adverse health effects, and found that prior to the implementation of this regulation, cancer risks are unacceptable for several communities. See section VI.F for an analysis that characterizes communities living in proximity to facilities and risks prior to implementation of the final regulation.

The EPA believes that this action is likely to reduce existing disproportionate and adverse effects on communities with EJ concerns. This action establishes standards for SCVs and ARVs at facilities where EtO use is less than 1 tpy, ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, CEVs, and room air emissions. In addition, it tightens standards for SCVs at facilities where EtO use is at least 1 tpy, as well as ARVs at facilities where EtO use is at least 10 tpy. This action also finalizes amendments to correct and clarify regulatory provisions related to emissions during periods of SSM, including removing general exemptions for periods of SSM and adding work practice standards for periods of SSM where appropriate. As a result of these changes, we expect zero people to be exposed to cancer risk levels above 100-in-1 million. See section IV for more information about the control requirements of the regulation and the resulting reduction in cancer risks.

The EPA additionally identified and addressed environmental justice concerns by engaging in outreach activities to communities we expect to be impacted most by the rulemaking The EPA is also requiring owners and operators of commercial sterilization facilities to submit electronic copies of required compliance reports, performance test reports, and performance evaluation reports, which will increase transparency and will provide greater access to information for the public, including impacted communities.

The information supporting this Executive order review is contained in section VI.F of this preamble, as well as in a technical report, *Analysis of Demographic Factors for Populations Living Near Ethylene Oxide Commercial Sterilization and Fumigation Operations,* available in the docket for this action.

K. Congressional Review Act (CRA)

This action is subject to the 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).

List of Subjects

40 CFR Part 60

Environmental protection, Administrative practice and procedures, Hazardous substances, Reporting and recordkeeping requirements.

40 CFR Part 63

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

Michael S. Regan,

Administrator.

For the reasons set forth in the preamble, the EPA amends 40 CFR parts 60 and 63 as follows:

PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

■ 1. The authority citation for part 60 continues to read as follows:

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

Appendix B to Part 60—Performance Specifications

■ 2. Appendix B to part 60 is amended by adding Performance Specification 19 to read as follows:

Appendix B to Part 60—Performance Specifications

* * * * *

Performance Specification 19-Performance Specifications and Test Procedures for Ethylene Oxide (ETO) Continuous Emission Monitoring Systems

1.0 Scope and Application

1.1 Analyte. This performance specification (PS) is applicable for measuring gaseous concentrations of Ethylene Oxide (EtO), CAS: 775–21–8, on a continuous basis in the units of the applicable standard or in units that can be converted to units of the applicable standard(s) (*e.g.,* lbs/hr,). This performance specification may be approved for the measurement of other pollutants and/or in other sectors by the Administrator on a case-by-case basis if not otherwise allowed or denied in an applicable subpart of the regulations.

1.2 Applicability.

1.2.1 This specification is used to evaluate the acceptability of EtO continuous emission monitoring systems (CEMS) at the time of installation or soon after and whenever specified in the regulations. The specification includes requirements for initial acceptance including instrument accuracy and stability assessments and use of audit samples if they are available.

1.2.2 The Administrator may require the operator, under section 114 of the Clean Air Act, to conduct CEMS performance evaluations at other times besides the initial test to evaluate the CEMS performance. See 40 CFR part 60, § 60.13(c) and § 63.8(e)(1).

1.2.3 A source that demonstrates their CEMS meets the criteria of this PS may use the system to continuously monitor gaseous EtO under any regulation or permit that requires compliance with this PS. If your CEMS reports the EtO concentration in the units of the applicable standard, no additional CEMS components are necessary. If your CEMS does not report concentrations in the units of the existing standard, then other CEMS (*i.e.,* oxygen) or CEMS components (*e.g.,* temperature, stack gas flow, moisture, and pressure) may be necessary to convert the units reported by your CEMS to the units of the standard.

1.2.4 These specification test results are intended to be valid for the life of the system. As a result, the EtO measurement system must be tested and operated in a configuration consistent with the configuration that will be used for ongoing continuous emissions monitoring.

1.2.5 Substantive changes to the system configuration require retesting according to this PS. Examples of such conditions include but are not limited to: major changes in dilution ratio (for dilution-based systems); changes in sample conditioning and transport, if used, such as filtering device design or materials; changes in probe design or configuration and changes in materials of construction. Changes consistent with instrument manufacturer upgrade that fall under manufacturer's certification do not require additional field verification. Manufacturer's upgrades (*e.g.,* changes to the quantification algorithm) require recertification by the manufacturer for those requirements allowed by this PS, including interference, and level of detection (LOD).

1.2.6 This specification is not designed to evaluate the ongoing CEMS performance, nor does it identify specific calibration techniques and auxiliary procedures to assess CEMS performance over an extended period of time. The requirements in Procedure 7 to Appendix F of this part are designed to provide a way to assess CEMS and CEMS components (if applicable) performance over an extended period of time. The source owner or operator is responsible to calibrate, maintain, and operate the CEMS properly.

2.0 Summary of Performance Specification

2.1 This specification covers the procedures that each EtO CEMS must meet during the performance evaluation test. Installation and measurement location specifications, data reduction procedures, and performance criteria are included.

2.2 The technology used to measure EtO must provide a distinct response and address any appropriate interference correction(s). It must accurately measure EtO in a representative sample of stack effluent.

2.3 The relative accuracy (RA) must be established against a reference method (RM) (*i.e.,* Method 320, or other alternative approved as a RM by the Administrator) on a case-by-case basis if not otherwise allowed or denied in an applicable subpart of the regulations.

2.4 A standard addition (SA) procedure using a reference standard is included in appendix A to this performance specification for use in verifying LOD. For extractive CEMS, where the SA is done by dynamic spiking (DS), the appendix A procedure is allowed as an option for assessing calibration drift and is also referenced by Procedure 7 of appendix F to this part for ongoing quality control tests.

3.0 Definitions

3.1 *Calibration drift* (CD) means the absolute value of the difference between the CEMS output response and an upscale reference gas or a zero-level gas, expressed as a percentage of the span value, when the CEMS is challenged after a stated period of operation during which no unscheduled adjustments, maintenance or repairs took place. For other parameters that are selectively measured by the CEMS (*e.g.,* temperature, velocity, pressure, flow rate) to measure in the units of the applicable standard, use two analogous values (*e.g.,* Low: 0–20% of full scale, High: 50–100% of full scale). 3.2 *Calibration Span* means the calibrated portion of the measurement range as specified in the applicable regulation or another requirement. If the span is not specified in the applicable regulation or other requirement, then it must be a value approximately equivalent to three times the applicable emission standard. When the emission standard is expressed as mass emissions, use the average flow rate in the duct to calculate the concentration equivalent of the emission standard.

3.3 *Centroidal area* means a central area that is geometrically similar to the stack or duct cross section and is no greater than 10 percent of the stack or duct cross-sectional area.

3.4 *Continuous Emission Monitoring System* (CEMS) means the total equipment required to measure the pollutant concentration or emission rate continuously. The system generally consists of the following three major subsystems:

3.4.1 *Sample interface* means that portion of the CEMS used for one or more of the following: Sample acquisition, sample transport, sample conditioning, and protection of the monitor from the effects of the stack effluent.

3.4.2 *EtO analyzer* means that portion of the EtO CEMS that measures the total vapor phase EtO concentration and generates a proportional output.

3.4.3 *Data recorder* means that portion of the CEMS that provides a permanent electronic record of the analyzer output. The data recorder may record other pertinent data such as effluent flow rates, various instrument temperatures or abnormal CEMS operation. The data recorder may also include automatic data reduction capabilities and CEMS control capabilities.

3.5 *Diluent gas* means a major gaseous constituent in a gaseous pollutant mixture. For combustion sources, either carbon dioxide (CO_2) or oxygen (O_2) or a combination of these two gases are the major gaseous diluents of interest.

3.6 *Dynamic spiking (DS)* means the procedure where a known concentration of EtO gas is injected into the probe sample gas stream for extractive CEMS at a known flow rate to assess the performance of the measurement system in the presence of potential interference from the flue gas sample matrix.

3.7 *Flow Rate Sensor* means that portion of the CEMS that senses the volumetric flow rate and generates an output proportional to that flow rate. The flow rate sensor shall have provisions to check the CD for each flow rate parameter that it measures individually (*e.g.,* velocity, pressure).

3.8 *Independent measurement(s)* means the series of CEMS data values taken during sample gas analysis separated by two times the procedure specific response time (RT) of the CEMS.

3.9 *Interference* means a compound or material in the sample matrix other than EtO whose characteristics may bias the CEMS measurement (positively or negatively). The interference may not prevent the sample measurement but could increase the analytical uncertainty in the measured EtO concentration through reaction with EtO or by changing the electronic signal generated during EtO measurement.

3.10 *Interference test* means the test to detect CEMS responses to interferences that are not adequately accounted for in the calibration procedure and may cause measurement bias.

3.11 *Level of detection (LOD)* means the lowest level of pollutant that the CEMS can

detect in the presence of the source gas matrix interferents with 99 percent confidence.

3.12 *Measurement error (ME)* is the mean difference between the concentration measured by the CEMS and the known concentration of a reference gas standard, divided by the span, when the entire CEMS, including the sampling interface, is challenged.

3.13 *Reference gas standard* means the gas mixture containing EtO at a known concentration and produced and certified in accordance with ''EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards,'' September 1997, as amended August 25, 1999, EPA–600/R–97/121 or more recent updates. The tests for analyzer measurement error, calibration drift, and system bias require the use of calibration gas prepared according to this protocol. If a zero gas is used for the low-level gas, it must meet the requirements under the definition for ''zero air'' in 40 CFR 72.2. Alternatively, if the ''protocol'' gas is not commercially available, you must use a reference gas that has been prepared according to the procedures in appendix B of this PS.

3.14 *Relative accuracy (RA)* means the absolute mean difference between the gas concentration, or the emission rate determined by the CEMS, and the value determined by the RM, plus the confidence coefficient of a series of nine test runs, divided by the average of the RM or the applicable emission standard.

3.15 *Response time (RT)* means the time it takes for the measurement system, while operating normally at its target sample flow rate, dilution ratio, or data collection rate to respond to a known step change in gas concentration, either from a low- or zero-level to a high-level gas concentration or from a high-level to a low or zero-level gas concentration, and to read 95 percent of the change to the stable instrument response. There may be several RTs for an instrument related to different functions or procedures (*e.g.,* DS, LOD, and ME).

3.16 *Span value* means an EtO concentration approximately equal to two times the concentration equivalent to the emission standard unless otherwise specified in the applicable regulation, permit or another requirement. Unless otherwise specified, the span may be rounded up to the nearest multiple of 5.

3.17 *Stable value* means the measure of two or more values that are statistically the same and the absence of measurement system drift.

3.18 *Standard addition* means the addition of known amounts of EtO gas (either statically or dynamically) measured sample gas stream.

3.19 *Zero gas* means a gas with an EtO concentration that is below the LOD of the measurement system.

4.0 Interferences

Sample gas interferences will vary depending on the instrument or technology used to make the measurement. Interferences must be evaluated through the interference test in this PS. Several compounds including carbon dioxide (CO_2), carbon monoxide (CO), methane (CH_4), and water (H_2O) are potential optical interferences with certain types of EtO monitoring technology.

Note: Interferences may be mitigated though the use of dilution systems, however this approach could also affect the sensitivity of the measurement.

5.0 Safety

The procedures required under this PS may involve hazardous materials, operations, and equipment. This PS may not address all the safety issues associated with these procedures. It is the responsibility of the user to establish appropriate safety and health practices and determine the applicable regulatory limitations prior to performing these procedures. The CEMS user's manual and as well as cautions within and materials recommended by the RM should be consulted for specific precautions to be taken in regard to the relative accuracy testing.

6.0 Equipment and Supplies

The equipment and supplies are the same as in section 6 of PS 18, except replace HCl for EtO where appropriate. The following definitions are added and/or revised:

6.1 Moisture Measurement System. If correction of the measured EtO emissions for moisture is required, you must install, operate, maintain, and quality assure a continuous moisture monitoring system for measuring and recording the moisture content of the flue gases. The following continuous moisture monitoring systems are acceptable: Any optical measurement system validated according to Method 301 or section 13.0 of Method 320 in appendix A to part 63 of this chapter; a continuous moisture sensor; an oxygen analyzer (or analyzers) capable of measuring O_2 both on a wet basis and on a dry basis; or other continuous moisture measurement methods approved by the Administrator.

7.0 Reagents and Standards

7.1 Reference Gases means the gas mixture containing EtO at a known concentration and produced and certified in accordance with ''EPA Traceability Protocol for Assay and Certification of Gaseous Standards, May 2012 (EPA 600/R–12/531) or more recent updates. The tests for analyzer measurement error, calibration drift, and system bias require the use of calibration gas prepared according to this protocol. If a zero gas is used for the low-level gas, it must meet the requirements under the definition for ''zero air'' in 40 CFR 72.2. Alternatively, if the ''protocol'' gas is not commercially available, you must use a reference gas that has been prepared according to the procedures in appendix B of this PS and meeting the requirements in section 12.2 of appendix B of this PS, if applicable.

7.2 Cylinder gas may be diluted for use in this specification, including measurement error testing. You must document the quantitative introduction of EtO standards into the system using Method 205, found in 40 CFR part 51, appendix M, or other procedure approved by the Administrator. The laboratory/field evaluations in Method 205 must be conducted at least quarterly and prior to any audit test (*e.g.,* CGA, RAA) required in QA Procedure 7 (40 CFR part 60, appendix F). Calibration must be conducted on an annual basis or whenever significant changes are made to the dilution system. In addition to the requirements in Method 205, when in use, you must document gas flow rates through each of the channels; if the dilution system records these values electronically, this is considered the documentation. For the purpose of this PS, cylinder gas should not be diluted beyond a dilution ratio of 500:1 using Method 205.

8.0 CEMS Measurement Location Specifications and Pretest Preparation

8.1 Prior to the start of your initial PS tests, you must ensure that the CEMS is installed according to the manufacturer's specifications and the requirements in this section.

8.2 CEMS Installation. Install the CEMS at an accessible location where the pollutant concentration or emission rate measurements are directly representative of the EtO emissions. If the units of the emission standard are expressed as a mass (*e.g.,* lb/hr), then the CEMS probe must also be located within 0.5 equivalent diameters of the flow sensor and the CEMS must be located (1) at least two equivalent diameters downstream from the nearest control device, the point of pollutant generation, or other point at which a change in the pollutant concentration or emission rate may occur and (2) at least a half equivalent diameter upstream from the effluent exhaust or control device. If the CEMS are to utilize time-sharing, the distance between each measurement point and the CEMS should be approximately the same. The CEMS need not be installed at the same location as the relative accuracy test location. If you fail the RA requirements in this specification due to the CEMS measurement location and a satisfactory correction technique cannot be established, the Administrator may require the CEMS to be relocated.

8.2.1 Single point sample gas extraction should be (1) no less than 1.0 m (3.3 ft.) from the stack or duct wall or (2) within the centroidal area of the stack or duct cross section.

8.2.2 CEMS and Data Recorder Scale Check. After CEMS installation, record and document the measurement range of the EtO CEMS. The CEMS operating range and the range of the data recording device must encompass all potential and expected EtO concentrations, including the concentration equivalent to the applicable emission limit and the span value.

9.0 Quality Control—Reserved

10.0 Calibration and Standardization—Reserved

11.0 Performance Specification Test Procedure

After completing the CEMS installation, setup, and calibration, you must complete the PS test procedures in this section. You must perform the following procedures and meet the performance requirements for the initial demonstration of your CEMS:

a. Interference Test;

b. Level of Detection Determination;

c. Response Time Test;

d. Measurement Error Test;
e. Calibration Drift Test; and
f. Relative Accuracy Test.
g. If CEMS is to be time-shared, determine the response time to each measurement point, the sampling time at each measurement point, and the cycle time at each measurement point. The sampling time at each measurement point shall be at least 3 times as long as the system response time (RT), and the maximum number of measurement points shall not exceed the quotient, rounded down to the next whole number, of 15 minutes divided by the longest cycle time of the measurement point.

11.1 *Interference Test*

11.1.1 Prior to its initial use in the field, you must demonstrate that your monitoring system meets the performance requirements of the interference test in section 13.5 of this PS to verify that the candidate system measures EtO accurately in the presence of common interferences in emission matrices from commercial sterilizers. In the event this performance specification is applied in other emission sources, the interference test must evaluate any other predominant gases is the emission matrices of those sources.

11.1.2 Your interference test must be conducted in a controlled environment. The equipment you test for interference must include the combination of the analyzer, related analysis software, and any sample conditioning equipment (*e.g.,* dilution module, moisture removal equipment or other interferent scrubber) used to control interferents.

11.1.3 If you own multiple measurement systems with components of the same make and model numbers, you need only perform this interference test on one analyzer and associated interference conditioning equipment combination. You may also rely on an interference test conducted by the manufacturer or a continuous measurement system integrator on a system having components of the same make(s) and model(s) of the system that you use.

11.1.4 Perform the interference check using an EtO reference gas concentration of approximately ten times the LOD or at 50 parts per billion, whichever is greater.

11.1.5 Introduce the interference test gases listed in table 1 in section 17.0 of this PS to the analyzer/conditioning system separately or in any combination. The interference test gases need not be of reference gas quality.

11.1.6 The interference test must be performed by combining an EtO reference gas with each interference test gas (or gas mixture). You must measure the baseline EtO response, followed by the response after adding the interference test gas(es) while maintaining a constant EtO concentration. You must perform each interference gas injection and evaluation in triplicate.

Note: The baseline EtO gas may include interference gases at concentrations typical of ambient air (*e.g.,* 21 percent O_2, 400 parts per million (ppm) CO_2, 2 percent H_2O), but these concentrations must be brought to the concentrations listed in table 1 of this PS when their interference effects are being evaluated.

11.1.7 You should document the gas volume/rate, temperature, and pressure used to conduct the interference test. A gas blending system or manifold may be used.

11.1.8 Ensure the duration of each interference test is sufficient to condition the EtO measurement system surfaces before a stable measurement is obtained.

11.1.9 Measure the EtO response of the analyzer/sample conditioning system combination to the test gases in ppbv. Record the responses and determine the overall interference response using table 2 in section 17.0 of this PS.

11.1.10 For each interference gas (or mixture), calculate the mean difference (ΔMC_{avg}) between the measurement system responses with and without the interference test gas(es) using equation 1 in section 12.2 of this PS. Summarize the results following the format contained in table 2 in section 17.

11.1.11 Calculate the percent interference (I) for the gas runs using equation 2 in section 12.2 of this PS.

11.1.12 The total interference response (*i.e.,* the sum of the interference responses of all tested gaseous components) must not exceed the criteria set forth in section 13.5 of this PS.

11.2 Level of Detection Determination

11.2.1 You must determine the minimum amount of EtO that can be detected above the background in a representative gas matrix.

11.2.2 You must perform the LOD determination in a controlled environment such as a laboratory or manufacturer's facility.

11.2.3 You must add interference gases listed in table 1 of this PS to a constant concentration of EtO reference gas.

11.2.3.1 You may not use an effective reference EtO gas concentration greater than ten times the estimated instrument LOD.

11.2.3.2 Inject the EtO and interferents described in section 11.1.5 of this PS directly into the inlet to the analyzer, allow time for the value to stabilize and then collect measurement data for 15 minutes and average those results. Repeat this procedure to obtain a total of seven or more of these runs, purging the measurement system with ambient air between each run, to determine the LOD.

11.2.4 Calculate the standard deviation of the measured values and define the LOD as three times the standard deviation of these measurements.

11.2.5 You must verify the controlled environment LOD of section 11.2.2 of this PS for your CEMS during initial setup and field certification testing using the SA procedure in appendix A of this PS with the following exceptions:

11.2.5.1 You must make three independent SA measurements spiking the native source concentration by no more than five times the controlled environment LOD concentration determined in section 11.2.4.

11.2.5.2 You must perform the SA as a dynamic spike by passing the spiked source gas sample through all filters, scrubbers, conditioners, and other monitoring system components used during normal sampling, and as much of the sampling probe as practical.

11.2.5.3 The amount detected, or standard addition response (SAR), is based on the average difference of the native EtO concentration in the stack or duct relative to the native stack concentration plus the SA. You must be able to detect the effective spike addition (ESA) above the native EtO present in the stack gas matrix. The ESA is calculated using equation A7 in appendix A of this PS.

11.2.5.4 If the field verification of your system LOD does not demonstrate a SAR greater than or equal to your initial controlled environment LOD, you must increase the SA concentration incrementally and repeat the field verification procedure until the SAR is equal to or greater than LOD. The site-specific standard addition detection level (SADL) is equal to the standard addition needed to achieve the acceptable SAR, and the SADL replaces the controlled environment LOD. The SADL is calculated as the ESA using equation A7 in appendix A of this PS. As described in section 13.1 of this PS, the controlled environment LOD or the SADL that replaces a controlled environment LOD must be less than 20 percent of the applicable emission limit.

11.3 Response Time Determination. You must determine ME– and SA–RT.

11.3.1 For ME–RT, start the upscale RT determination by injecting zero gas into the measurement system as required by the procedures in section 11.4 of this PS. For the SA–RT start the upscale RT determination at native stack concentration of EtO. Allow the value to stabilize, which for the purpose of this PS is a change no change greater than 1.0 percent of span or 10 ppbv (whichever is greater) for 30 seconds.

11.3.2 When the CEMS output has stabilized, record the response in ppbv, record the time (hh:mm:ss), and immediately introduce an upscale (high level) or spike reference gas as required by the relevant (ME–RT or SA–RT) procedure. Record the time (hh:mm:ss) required for the measurement system to reach 95 percent of the change to the final stable value, the difference in these times is the upscale RT.

11.3.3 Reintroduce the zero gas for the ME–RT or stop the upscale gas flow for the SA–RT and immediately record the time (hh:mm:ss). Record the time (hh:mm:ss) required to reach within 95 percent of the previous stable response in 11.3.1 or 10 ppbv (whichever is greater); the difference in these times is the downscale RT.

Note: For CEMS that perform a series of operations (purge, blow back, sample integration, analyze, etc.), you must start adding reference or zero gas immediately after these procedures are complete.)

11.3.4 Repeat the entire procedure until you have three sets of data, then determine the mean upscale and mean downscale RTs for each relevant procedure (from each measurement point if the CEMS is time-sharing). Report the greater of the average upscale or average downscale RTs as the RT for the system.

11.4 Measurement Error (ME) Test

11.4.1 The measurement error test must be performed at the same time as the calibration drift test when the system is being placed in service. The measurement error test must be performed any time a substantive change (see section 1.2.5) has been made to the measurement system.

11.4.1.1 Introduce reference gases to the CEMS probe, prior to the sample

conditioning and filtration system. You may use a gas dilution system meeting the requirement in section 7.2 of this PS.

11.4.1.2 Challenge the measurement system with a zero gas and at the three upscale EtO reference gas concentrations in the range shown in table 3 of this PS. You may introduce different reference gas concentrations in any order, but you must not introduce the same gas concentration twice in succession.

11.4.1.3 Introduce the calibration gas into the sampling probe with sufficient flow rate to replace the entire source gas sample and continue the gas flow until the response is stable, as evidenced when the difference between two consecutive measurements is within 1.0 percent of span or 5 ppbv (whichever is less). Record this value and inject the next calibration gas.

11.4.1.4 Make triplicate measurements for each reference gas for a total of twelve measurements.

11.4.1.5 At each reference gas concentration, determine the average of the three CEMS responses (MC_l). Calculate the ME using equation 3A in section 12.3.

11.4.1.6 For non-dilution systems, you may adjust the system to maintain the correct flow rate at the analyzer during the test, but you may not make adjustments for any other purpose. For dilution systems, you must operate the measurement system at the appropriate dilution ratio during all system ME checks, and you may make only the adjustments necessary to maintain the proper ratio.

11.4.2 You may use table 5 in section 17.0 to record and report your ME test results.

11.4.3 If the ME specification in section 13.3 is not met for all four reference gas concentrations, take corrective action, and repeat the test until an acceptable 4-level ME test is achieved.

11.5 Seven-Day Calibration Drift (CD) Test

11.5.1 The CD Test Period. Prior to the start of the RA tests, you must perform a seven-day CD test. The purpose of the seven-day CD test is to verify the ability of the CEMS to maintain calibration for each of seven consecutive unit operating days as specified in section 11.5.5 of this PS.

11.5.2 The CD tests must be performed using the zero gas and high-level reference gas standards as defined in table 3 of this PS.

11.5.3 Conduct the CD test on each day during continuous operation of the CEMS and normal facility operations following the procedures in section 11.7 of this PS, except that the zero gas and high-level gas need only be introduced to the measurement system once each for the seven days.

11.5.4 If periodic automatic or manual adjustments are made to the CEMS zero and upscale response factor settings, conduct the CD test immediately before these adjustments.

Note: Automatic signal or mathematical processing of all measurement data to determine emission results may be performed throughout the entire CD process.

11.5.5 Determine the magnitude of the CD at approximately 24-hour intervals, for 7 consecutive unit operating days. The 7 consecutive unit operating days need not be 7 consecutive calendar days.

11.5.6 Record the CEMS response for single measurements of zero gas and high-level reference gas. You may use table 6 in section 17 of this PS to record and report the results of your 7-day CD test. Calculate the CD using equation 3B in section 12.3. Report the absolute value of the differences as a percentage of the span value.

11.5.7 The zero-level and high-level CD for each day must be less than 5.0 percent of the span value or an absolute difference of 10 ppbv, as specified in section 13.2 of this PS. You must meet this criterion for 7 consecutive operating days.

11.5.8 Dynamic Spiking Option for Seven-Day CD Test. You have the option to conduct a high-level dynamic spiking procedure for each of the 7 days in lieu of the high-level reference gas injection described in sections 11.5.2 and 11.5.3. If this option is selected, the daily zero CD check is still required.

11.5.8.1 To conduct each of the seven daily mid-level dynamic spikes, you must use the DS procedure described in appendix A of this PS using a single spike chosen to yield the range as indicated in table 3.

11.5.8.2 You must perform the dynamic spike procedure by passing the spiked source gas sample through all filters, scrubbers, conditioners, and other monitoring system components used during normal sampling, and as much of the sampling probe as practical.

11.5.8.3 Calculate the high-level CD as a percent of span using equation A6 of appendix A to this PS and calculate the zero-drift using equation 3B in section 12.3. Record and report the results as described in sections 11.5.6 and 11.5.7.

11.6 Relative Accuracy Test

11.6.1 Unless otherwise specified in an applicable regulation, use Method 320 as the RM for EtO measurement. Conduct the RM tests in such a way that they will yield results representative of the emissions from the source that can be compared to the CEMS data. You must collect gas samples that are at stack conditions (hot and wet), and you must traverse the stack or duct as required in section 11.6.3.

11.6.2 Conduct the diluent (if applicable), moisture (if needed), and pollutant measurements simultaneously. If the emission standard is expressed in a mass unit (*i.e.,* lb/hr) you must also determine the flowrate simultaneously with each test using Method 2, 2A, 2B, 2C or 2D in appendix A–1 to this part, as applicable.

11.6.3 Reference Method Measurement Location and Traverse Point(s) Selection.

11.6.3.1 Measurement Location. Select, as appropriate, an accessible RM measurement location at least two equivalent diameters downstream from the nearest control device, point of pollutant generation, or other point at which a change in the pollutant concentration or emission rate may occur, and at least one-half equivalent diameter upstream from the effluent exhaust or a control device. When pollutant concentration changes are due solely to diluent leakage (*e.g.,* air heater leakages) and pollutants and diluents are simultaneously measured at the same location, a half diameter may be used in lieu of two equivalent diameters. The equivalent duct diameter is calculated according to Method 1 in appendix A–1 to this part. The CEMS and RM sampling locations need not be the same.

11.6.3.2 Traverse Point Selection. Select traverse points that assure acquisition of representative RM samples over the stack or duct cross section according to one of the following options: (a) sample at twelve traverse points located according to section 11.3 of Method 1 in appendix A–1 to this part or (b) sample at the three traverse points at 16.7, 50.0, and 83.3 percent of the measurement line. Alternatively, you may conduct a stratification test following the procedures in sections 11.6.3.2.1 through 11.6.3.2.4 to justify sampling at a single point. Stratification testing must be conducted at the sampling location to be used for the RM measurements during the RA test and must be made during normal facility operating conditions. You must evaluate the stratification by measuring the gas on the same moisture basis as the EtO CEMS (wet or dry). Stratification testing must be repeated for each RA test program to justify single point.

11.6.3.2.1 Use a probe of appropriate length to measure the EtO concentration, as described in this section, using 12 traverse points located according to section 11.3 of Method 1 in appendix A–1 to this part for a circular stack or nine points at the centroids of similarly shaped, equal area divisions of the cross section of a rectangular stack.

11.6.3.2.2 Calculate the mean measured concentration for all sampling points (MN_{avg}).

11.6.3.2.3 Calculate the percent stratification (S_t) of each traverse point using equation 5 in section 12.5.

11.6.3.2.4 The gas stream is considered to be unstratified and you may perform the RA testing at a single point that most closely matches the mean if the concentration at each traverse point differs from the mean measured concentration for all traverse points by no more than 5.0 percent of the mean concentration of EtO or 10 ppbv, whichever is less restrictive.

11.6.4 In order to correlate the CEMS and RM data properly, record the beginning and end of each RM run (including the time of day in hours, minutes, and seconds) using a clock synchronized with the CEMS clock used to create a permanent time record with the CEMS output.

11.6.5 You must conduct the RA test during representative process and control operating conditions or as specified in an applicable regulation, permit or subpart.

11.6.6 Conduct a minimum of nine RM test runs.

Note: More than nine RM test runs may be performed. If this option is chosen, up to three test run results may be excluded so long as the total number of test run results used to determine the CEMS RA is greater than or equal to nine. However, all data must be reported including the excluded test runs.

11.6.7 Analyze the results from the RM test runs using equations 9 through14 in section 12.6. Calculate the RA between the CEMS results and the RM results.

11.7 Record Keeping and Reporting

11.7.1 Record the results of the CD test, the RT test, the ME test, and the RA test. Also keep records of the RM and CEMS field data, calculations, and reference gas certifications necessary to confirm that the performance of the CEMS met the performance specifications.

11.7.2 For systems that use Method 205 to prepare EtO reference gas standards, record results of Method 205 performance test field evaluation, reference gas certifications, and gas dilution system calibration.

11.7.3 Record the LOD and field verified SADL for the CEMS in ppbv.

11.7.4 Record the results of the interference test.

11.7.5 Report the results of all certification tests to the appropriate regulatory agency (or agencies), in hardcopy and/or electronic format, as required by the applicable regulation or permit.

12.0 Calculations and Data Analysis

12.1 Nomenclature.

C_i = Zero or EtO reference gas concentration used for test i (ppbv);

CC = Confidence coefficient (ppbv);

CD = Calibration drift (percent);

d_{avg} = Mean difference between CEMS response and the reference gas (ppbv);

d_i = Difference of CEMS response and the RM value (ppbv or units of emission standard, as applicable);

I = Total interference from major matrix stack gases (percent);

ΔMC_{avg} = Average of the 3 absolute values of the difference between the measured EtO calibration gas concentrations with and without interference from selected stack gases (ppbv);

MC_i = Measured EtO (or zero) reference gas concentration i (ppbv);

$\overline{MC}_i$ = Average of the measured EtO (or zero) reference gas concentration i (ppbv);

MC_{int} = Measured EtO concentration of the EtO reference gas plus the individual or combined interference gases (ppbv);

ME = Measurement error for CEMS (percent);

MN_{avg} = Average concentration at all sampling points (ppbv);

MN_{bi} = Measured native concentration bracketing each calibration check measurement (ppbv);

MN_i = Measured native concentration for test or run I (ppbv);

n = Number of measurements in an average value;

RA = Relative accuracy of CEMS compared to a RM (percent);

RM_{avg} = Mean measured RM value (ppbv) or units of the emission standard);

RM_i = RM concentration for test run i (ppbv or units of the emission standard);

S = Span value (ppmv);

S_d = Standard deviation of the differences (ppmv);

S_{ti} = Stratification at traverse point i (percent);

SADL = Standard addition detection level (ppmv);

$t_{0.975}$ = One-sided t-value at the 97.5th percentile obtained from table 4 in section 17.0 for n-1 measurements;

12.2 Calculate the difference between the measured EtO concentration with and without interferents for each interference gas (or mixture) for your CEMS as:

$$\Delta MC_{avg}=\frac{\sum_{i=1}^{3}|MC_i-MC_{int}|}{3} \quad \text{Eq. 1}$$

Calculate the total percent interference as:

$$I=\sum_{i=1}^{n}\frac{\Delta MC_{avg}}{\overline{MC}_i}x100 \quad \text{Eq. 2}$$

12.3 Calculate the ME or CD at Concentration i as:

$$ME=\frac{|C_i-\overline{MC}_i|}{S} \quad \text{Eq. 3A}$$

$$CD=\frac{|C_i-MC_i|}{S} \quad \text{Eq. 3B}$$

12.4 Calculate the average native concentration before and after each calibration check measurement as:

$$MN_{bi}=\frac{MN_i+MN_{i+1}}{2} \quad \text{Eq. 4}$$

12.5 Calculate the Percent Stratification at Each Traverse Point as:

$$S_{ti}=\frac{|MN_i-MN_{avg}|}{MN_{avg}} \quad \text{Eq. 5}$$

12.6 Calculate the RA Using RM and CEMS Data

12.6.1 Determine the CEMS final integrated average pollutant concentration or emission rate for each RM test period. Consider system RT, if important, and confirm that the results have been corrected to the same moisture, temperature, and diluent concentration basis, as applicable. If the emission standard is based on a mass emission (*i.e.,* lbs/hr), confirm the results have been calculated correctly.

12.6.3 Make a direct comparison of the average RM results and CEMS average value for identical test periods.

12.6.4 For each test run, calculate the arithmetic difference of the RM and CEMS results using equation 6.

$$d_i = RM_i - MN_i \qquad \text{Eq. 6}$$

12.6.5 Calculate the standard deviation of the differences (S_d) of the CEMS measured results and RM results using equation 7.

$$S_d = \sqrt{\frac{\sum_i^n \left(d_i - \left(\sum_{i=1}^n d_i\right)\right)^2}{n-1}} \qquad \text{Eq. 7}$$

12.6.6 Calculate the confidence coefficient (CC) for the RA test using equation 8.

$$CC = t_{0.975}\left(\frac{S_d}{(n^{1/2})}\right) \qquad \text{Eq. 8}$$

12.6.7 Calculate the mean difference (d_{avg}) between the RM and CEMS values in the units of ppbv or of the emission standard using equation 9.

$$d_{avg} = \frac{1}{n}\sum_{i=1}^{n} d_i \qquad \text{Eq. 9}$$

12.6.8 Calculate the average RM value using equation 10.

$$RM_{avg} = \frac{1}{n}\sum_{i=1}^{n} RM_i \qquad \text{Eq. 10}$$

12.6.9 Calculate RA of the CEMS using equation 11.

$$RA = \left[\frac{(|d_{avg}| + CC)}{RM_{avg}}\right] x100 \qquad \text{Eq. 11}$$

13.0 Method Performance

13.1 Level of Detection. You may not use a CEMS whose LOD or SADL is greater than 20 percent of the applicable regulatory limit or other action level for the intended use of the data. If the regulatory limit is not based on a concentration, document the calculated concentration equivalent as required in section 11.7.

13.2 Calibration Drift. The zero- and high-level calibration drift for the CEMS must not exceed 5.0 percent of the span value or an absolute difference of 10.0 ppbv for 7 consecutive operating days.

13.3 Measurement Error. The ME must be less than or equal to 5.0 percent of the span or an absolute difference of 10.0 ppbv value at the low-, mid-, and high-level reference gas concentrations.

13.4 Relative Accuracy. Unless otherwise specified in an applicable regulation or permit, the RA of the CEMS, whether calculated in units of EtO concentration or in units of the emission standard, must be less than or equal to 20.0 percent of the RM when RM_{avg} is used in the denominator of equation 11.

13.4.1 In cases where the RA is calculated on a concentration (ppmv) basis, if the average RM emission level for the test is less than 50 percent of the EtO concentration equivalent to the emission standard, you may substitute the EtO concentration equivalent to the standard in the denominator of equation 14 in place of RM_{avg}.

13.4.2 Similarly, if the RA is calculated in units of the emission standard and the EtO emission level measured by the RMs is less than 50 percent of the emission standard, you may substitute the emission standard in the denominator of equation 14 in place of RM_{avg}.

13.4.3 The alternative calculated RA in paragraph 13.4.1 or 13.4.2 must be less than or equal to 15.0 percent.

13.5 Interference Test.

13.5.1 The sum of the interference response(s) from equation 2 must not be greater than 2.5 percent of the calibration span or ±3.0 percent of the equivalent EtO concentration used for the interference test, whichever is less restrictive. The results are also acceptable if the sum of the interference response(s) does not exceed ten times the LOD or 30 ppbv.

14.0 Pollution Prevention—[Reserved]

15.0 Waste Management—[Reserved]

16.0 Bibliography

1. ‘‘Method 301—Field Validation of Pollutant Measurement Methods from Various Waste Media,’’ 40 CFR part 63, appendix A.

2. EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards, U.S. Environmental Protection Agency office of Research and Development, EPA/600/R–12/531, May 2012.

17.0 Tables, Diagrams, Flowcharts, and Validation Data

TABLE 1—INTERFERENCE TEST GAS CONCENTRATIONS

Potential interferent gas [1]	Approximate concentration (balance N_2)
CO_2	1% ± 0.2% CO_2.
CH_4	20 ± 5 ppm.
H_2O	5% ± 1% H_2O.[1]
N_2	Balance.[1]

[1] Any of these specific gases can be tested at a lower level if the manufacturer has provided reliableness for limiting or scrubbing that gas to a specified level in CEMS field installations.

TABLE 2—EXAMPLE INTERFERENCE TEST DATA SHEET

Date of Test	
Analyzer type	
Model Number	
Serial Number	
Span	
Test Organization	
Test Personnel	

Interference gas or combination	EtO concentration (ppbv)	EtO concentration w/interference (ppbv)	Absolute difference (ppbv)	Average absolute difference (ppbv)

Interference gas or combination	EtO concentration (ppbv)	EtO concentration w/interference (ppbv)	Absolute difference (ppbv)	Average absolute difference (ppbv)

TABLE 3—PERFORMANCE SPECIFICATION TEST ZERO AND REFERENCE GAS RANGES

Test	Units	EtO zero and reference gas concentrations in terms of percent of span [a]				Section
		Zero	Low level	Mid-level	High level	
Calibration Drift	% Of Span	<LOD	NA		[b] 80–100	11.5
Measurement Error	% Of Span	NA	20–30	50–60	80–100	11.4

[a] Reference gas concentration must be NIST traceable. (See section 7.1)
[b] High-level is required. For DS calibration drift option, choose a concentration that yields a value in this range at the analyzer.

TABLE 4—STUDENT'S t-VALUES

n – 1 [a]	t-value	n – 1 [a]	t-value	n – 1 [a]	t-value
1	12.71	11	2.201	21	2.080
2	4.303	12	2.179	22	2.074
3	3.182	13	2.160	23	2.069
4	2.776	14	2.145	24	2.064
5	2.571	15	2.131	25	2.060
6	2.447	16	2.120	26	2.056
7	2.365	17	2.110	27	2.052
8	2.306	18	2.101	28	2.048
9	2.262	19	2.093	29	2.045
10	2.228	20	2.086	30	2.042

[a] The value n is the number of independent pairs of measurements. Either discrete (independent) measurements in a single run or run averages can be used.

TABLE 5—MEASUREMENT ERROR TEST DATA

Source:			Date:		
CEMS:			Location:		
Serial Number:			Span:		
Run number	Reference gas value (ppbv)	CEMS response (ppbv)	Difference—low (ppbv)	Difference—low (ppbv)	Difference—low (ppbv)
1					
2					
3					
4					
5					
6					
7					
8					

TABLE 5—MEASUREMENT ERROR TEST DATA—Continued

Source:			Date:		
CEMS:			Location:		
Serial Number:			Span:		
Run number	Reference gas value (ppbv)	CEMS response (ppbv)	Difference—low (ppbv)	Difference—low (ppbv)	Difference—low (ppbv)
9					
Mean Difference—ppbv					
Measurement Error—%					

TABLE 6—CALIBRATION DRIFT TEST DATA

Source/Location:						
CEMS:						
Instrument Serial Number:						
Instrument Span:						
Day	Date	Time	Reference gas value (ppbv)	CEMS response (ppbv)	Difference (ppbv)	Percent of span
Zero Gas						
1			0			
2			0			
3			0			
4			0			
5			0			
6			0			
7			0			
High-Level Gas						
1						
2						
3						
4						
5						
6						
7						

PS–19 Appendix A Standard Addition Procedures

1.0 Scope and Application

1.1 This appendix A (appendix PS–19A) to Performance Specification 19 (PS–19) describes the procedure and performance requirements for standard addition (SA) as a quality check for ethylene oxide (EtO) continuous emission monitoring systems (CEMS).

1.2 This procedure must be used, as a level of detection (LOD) verification of all field-installed CEMS. Additionally, it is allowed by Procedure 7 in appendix F to this part as an alternative to upscale calibration drift (CD) tests, cylinder gas audits and relative accuracy audits (RAAs), and may be used for quality assurance purposes under other applicable regulations or permits that require EtO monitoring.

2.0 Summary of the Appendix for Standard Addition

As used here, SA is a gas phase method of standard additions (either static or dynamic) used to verify the accuracy of CEMS measurements in the presence of the sample matrix. For extractive CEMS, it consists of spiking a known quantity of EtO dynamically into the measurement system as an addition to the native EtO and the native source gas matrix.

3.0 Definitions

(See PS–19 and Procedure 7 of appendix F to this part for the Definitions Used in this appendix.)

4.0 Interferences

Interferences are discussed in PS–19, section 4.0.

5.0 Safety

The procedures required under this appendix may involve hazardous materials,

operations, and equipment. This procedure may not address all of the safety problems associated with these procedures. You as the facility or operator must establish appropriate safety and health practices and determine the applicable regulatory limitations prior to performing these procedures. As the CEMS user, you should consult instrument operation manuals, material safety data sheets, compressed gas safety requirements, and other Occupational Safety and Health Administration regulations for specific precautions to be taken.

6.0 Equipment and Supplies

An example of equipment and supplies is described in section 6 of PS–18.

7.0 Reagents and Standards

SA materials must meet the requirements defined for reference gases in section 7 of PS–19 to perform this procedure.

8.0 Standard Addition and Dynamic Spiking Procedure

The standard addition procedure consists of measuring the native source gas concentration, addition of reference gas, and measurement of the resulting SA elevated source gas concentration. EtO is spiked dynamically and thus, one must account for the dilution of sample gas from the addition of the EtO reference gas.

8.1 SA Concentration and Measurement Replicates.

8.1.1 You must inject EtO gas to create a measured concentration based on the requirements of the particular performance test (*e.g.,* LOD verification, CD).

8.1.2 Each dynamic spike (DS) or standard addition (SA) replicate consists of a measurement of the source emissions concentration of EtO (native stack concentration) with and without the addition of EtO. With a single CEMS, you must alternate the measurement of the native and SA-elevated source gas so that each measurement of SA-elevated source gas is immediately preceded and followed by a measurement of native stack gas. Introduce the SA gases in such a manner that the entire CEMS is challenged. Alternatively, you may use an independent continuous EtO monitor to measure the native source concentration before and after each standard addition as described in section 8.1.4.

8.1.3 Unless specified otherwise by an applicable rule, your SA-elevated concentration may not exceed 100 percent of span when the SA and native EtO concentration are combined.

8.1.4 As an alternative to making background measurements pre- and post-SA, you may use an independent continuous EtO monitor as a temporary unit to measure native stack EtO concentration while simultaneously using the CEMS to measure the SA-elevated source concentration. If you use an independent continuous EtO monitor you must make one concurrent background or native EtO measurement using both the installed CEMS and the independent continuous EtO monitor, immediately before the SA procedure in section 8.2 or 8.3 begins, to confirm that the independent monitoring system measures the same background concentration as the CEMS being qualified with this PS.

8.2 Dynamic Spiking Procedure.

8.2.1 Your EtO spike addition must not alter the total volumetric sample system flow rate or basic dilution ratio of your CEMS (if applicable).

8.2.2 Your spike gas flow rate must not contribute more than 10 percent of the total volumetric flow rate through the CEMS.

8.2.3 You must determine a dilution factor (DF) or relative concentration of EtO for each dynamic spike. Calibrated, NIST-traceable flow meters accurate to within 2.0 percent or highly accurate tracer gas measurements are required to make the necessary DF determinations at the accuracy required for this PS. Calibrated, NIST-traceable flow meters (*e.g.,* venturi, orifice) accurate to within 2.0 percent should be recertified against an NIST-traceable flow meter annually. Note: Since the spiking mass balance calculation is directly dependent on the accuracy of the DF determination, the accuracy of measurements required to determine the total volumetric gas flow rate, spike gas flow rate, or tracer gas standard addition concentration is critical to your ability to accurately perform the DS procedure and calculate the results.

8.2.4 You must monitor and record the total sampling system flow rate and sample dilution factor (DF) for the spiking and stack gas sampling systems to ensure they are known and do not change during the spiking procedure. Record all data on a data sheet similar to table A1 in section 13 of this appendix.

8.2.4.1 You may either measure the spike gas flow and the total flow with calibrated flow meters capable of NIST traceable accuracy to ±2.0 percent or calculate the flow using a stable tracer gas included in your spike gas standard.

8.2.4.2 If you use flow measurements to determine the spike dilution, then use equation A1 in section 11.2.1 of this appendix PS–19A to calculate the DF. Determination of the spike dilution requires measurement of EtO spike flow (Q_{spike}) and total flow through the CEM sampling system (Q_{probe}).

8.2.4.3 If your CEMS is capable of measuring an independent stable tracer gas, you may use a spike gas that includes the tracer to determine the DF using equation A2 or A3 (sections 11.2.2 and 11.2.3 of this appendix PS–19A) depending on whether the tracer gas is also present in the native source emissions.

8.2.4.4 For extractive CEMS, you must correct the background measurements of EtO for the dilution caused by the addition of the spike gas standard. For spiking systems that alternate between addition of EtO and zero gas at a constant DF, the background measurements between spikes will not be equal to the native source concentration.

8.2.5 Begin by collecting unspiked sample measurements of EtO. You must use the average of two unspiked sample measurements as your pre-spike background.

Note: Measurements should agree within 5.0 percent or three times the level of detection to avoid biasing the spike results.

8.2.5.1 Introduce the EtO gas spike into the permanent CEMS probe, upstream of the particulate filter or sample conditioning system and as close to the sampling inlet as practical.

8.2.5.2 Maintain the EtO gas spike for at least twice the DS response time of your CEMS or until the consecutive measurements agree within 5.0 percent. Collect two independent measurements of the native plus spiked EtO concentration.

8.2.5.3 Stop the flow of spike gas for at least twice the DS response time of your CEMS or until the consecutive measurements agree within 5.0 percent. Collect two independent measurements of the native EtO concentration.

8.2.6 Repeat the collection of sample measurements in section 8.2.5 until you have data for each spike concentration including a final set of unspiked sample measurements according to section 8.2.5.3.

8.2.7 Verify that the CEMS responded as expected for each spike gas injection, and that the data quality is not impacted by large shifts in the native source concentration. Discard and repeat any spike injections as necessary to generate a complete set of the required replicate spike measurements.

8.2.8 Calculate the standard addition response (SAR) for extractive CEMS, using equation A4 in section 11.2, of this appendix PS–19A.

8.2.9 If the DS results do not meet the specifications for the appropriate performance test in PS–19 or Procedure 7 of appendix F of this part, you must take corrective action and repeat the DS procedure.

9.0 Quality Control—Reserved

10.0 Calibration and Standardization—Reserved

11.0 Calculations and Data Analysis

Calculate the SA response for each measurement and its associated native EtO measurement(s), using equations in this section. (Note: For cases where the emission standard is expressed in units of lb/hr or corrected to a specified O_2 or CO_2 concentration, an absolute accuracy specification based on a span at stack conditions may be calculated using the average concentration and applicable conversion factors. The appropriate procedures for use in cases where a percent removal standard is more restrictive than the emission standard is the same as in PS–2, sections 12 and 13, in this appendix.)

11.1 Nomenclature.

C_{spike} = Actual EtO reference gas concentration spiked (*e.g.,* bottle or reference gas concentration) ppmv;

$C_{tracer\ spiked}$ = Tracer gas concentration injected with spike gas (''reference concentration'') ppmv;

DF = Spiked gas dilution factor;

DSCD = Calibration drift determined using DS procedure (percent);

DSE = Dynamic spike error (ppmv);

ESA = Effective spike addition (ppmv);

MC_{SA} = Measured SA-elevated source gas concentration (ppmv);

MC_{spiked} = Measured EtO reference gas concentration i (ppmv);

MC_{native} = Average measured concentration of the native EtO (ppmv);

$M_{native\ tracer}$ = Measured tracer gas concentration present in native effluent gas (ppmv);

$M_{spiked\ tracer}$ = Measured diluted tracer gas concentration in a spiked sample (ppmv);

Q_{spike} = Flow rate of the dynamic spike gas (Lpm);

Q_{probe} = Average total stack sample flow through the system (Lpm);

S = Span (ppmv);

SAR = Standard addition response (ppmv)

11.2 Calculating Dynamic Spike Response and Error.

11.2.1 If you determine your spike DF using spike gas and stack sample flow measurements, calculate the DF using equation A1:

$$DF=\frac{Q_{spike}}{Q_{probe}} \quad \text{Eq. A1}$$

11.2.2 If you determine your spike DF using an independent stable tracer gas that is not present in the native source emissions, calculate the DF for DS using equation A2:

$$DF=\frac{M_{spiked\ tracer}}{C_{tracer\ spiked}} \quad \text{Eq. A2}$$

11.2.3 If you determine your spike dilution factor using an independent stable tracer that is present in the native source emissions, calculate the dilution factor for dynamic spiking using equation A3:

$$DF=\frac{M_{spiked\ tracer} - M_{native\ tracer} -}{C_{tracer\ spiked} - M_{native\ tracer}} \quad \text{Eq. A3}$$

11.2.4 Calculate the SA response using equation A4:

$$SAR=MC_{spiked}-(1-DF)xMC_{native} \quad \text{Eq. A4}$$

11.2.5 Calculate the DS error using equation A5.

$$DSE=MC_{spiked}-MC_{native}-DFx(C_{spike}-MC_{native}) \quad \text{Eq. A5}$$

11.2.6 Calculating CD using DS. When using the DS option for determining mid-level CD, calculate the CD as a percent of span using equation A6:

$$DCSD=\frac{|DSE|}{S} \quad \text{Eq. A6}$$

11.2.7 The effective spike addition (ESA) is the expected increase in the measured concentration as a result of injecting a spike. Calculate ESA using equation A7:

$$ESA=DF(C_{spike}-MC_{native}) \quad \text{Eq. A7}$$

12.0 Reserved

13.0 Tables and Figures

TABLE A13—1—SPIKE DATA SHEET

Facility Name:	Date:	Time:
Unit(s) Tested:	Personnel:	
Analyzer Make and Mode		

TABLE A13—1—SPIKE DATA SHEET—Continued

Serial Number		
Calibration Span		

Q_{probe} (lpm)	Q_{spike} (lpm)	DF [1]	MC_{native}			Actual value (ppb)		DSE (ppbv)
			Pre	Post	Avg.	C_{spike} [2]	MC_{spike} [3]	
							Average	
							SD	

[1] DF must be less than or equal to 10%.
[2] C_{spike} = Actual EtO concentration of the spike gas, ppbv.
[3] MC_{spike} = Measured EtO concentration of the spiked sample at the target level, ppbv.

PS–19 Appendix B Preparation and Certification of Ethylene Oxide Gas Standards

1.0 Scope and Application

1.1 This appendix (appendix PS–19B) to Performance Specification 19 (PS–19) describes the procedure and performance criteria for the preparation and certification of EtO Gas Manufacturer Primary Standards (GMPS) and Gas Manufacturer Alternative Certified Standards (GMACS). These procedures are not specific to ethylene oxide and could be transferable to the preparation of gas standards for other pollutants regulated under 40 CFR parts 59, 60, 61, 63, and 65.

2.0 Summary of the Appendix

EPA requires the use of EPA Protocol gas standards for emissions monitoring. These gases are established following the EPA Traceability Protocol for Assay and Certification of Gaseous Standards, May 2012 (EPA 600/R–12/531) otherwise referred in this appendix PS–19B as the EPA Traceability Protocol. The EPA Traceability Protocol requires the use of certified reference gas standards directly traceable to National Institute of Standards and Technology (NIST) or other recognized national metrology institute (NMI) reference gas standards. A NIST certified value is a value for which NIST has the highest confidence in that all known or suspected sources of bias and imprecision have been accounted for. Without NIST or other NMI reference gas standards, the necessary EPA Protocol gas standards cannot be prepared. An alternative approach is needed to establish a gas standard functionally equivalent to the EPA Protocol gas standard when NIST or NMI reference gas standard are not available. This appendix PS–19B is intended to provide procedures and performance criteria for the establishment of Gas Manufacturer Alternative Certified Standards (GMACS), the functional equivalent of EPA Protocol gas standards. GMACS and Gas Manufacturer Primary Standards (GMPS), the functional equivalent of the NIST or NMI reference gas standards. The GMPS are the reference gases used to establish the certified concentrations of the GMACs. The GMPS are established using a dual certification approach where the gravimetrically prepared reference value is confirmed using an independent measurement approach traceable to the International System of Units (SI) and references materials or devices.

2.1 This appendix PS–19B is intended to be performance-based and allow specialty gas manufacturers (SGM) flexibility in the preparation and certification of GMPS and GMACS.

2.2 This appendix PS–19B is not intended to be a replacement for the EPA Protocol gases established according to the EPA Traceability Protocol when calibration gases that meet EPA Traceability Protocol requirements are available. When NIST or other recognized NMI reference gas standards are manufactured and readily available, those gases must be used.

2.3 This appendix PS–19B is reliant on the procedures included the EPA Traceability Protocol for Assay and Certification of Gaseous Standards, May 2012 (EPA 600/R–12/531). Users of this appendix PS–19B for the preparation of GMPS and GMACS must be proficient with the preparation protocol cylinders using this standard.

Note: This appendix PS–19B does not require the user to participate in any protocol gas verification program.

2.4 Any alternatives to the procedures in this appendix PS–19B are subject to Administrator review under the alternative test method the authority to approve alternatives or changes to test methods specified in the General Provisions to 40 CFR parts 60, 61, and 63 (§§ 60.8(b)(2), 61.13(h)(1)(ii), and 63.7(e)(2)(ii)). Requests for alternative to the procedures must be submitted to the agency according to Guideline Document 22 (*https://www.epa.gov/system/files/documents/2022-09/gd-022r5.pdf*).

3.0 Definitions

3.1 *Certification* means a set of procedures and performance criteria used by a SGM to prepare and certify a GMPS and/or GMACS for commercial sale.

3.2 *Certified Reference Material or CRM* means a material that has been certified or verified by either NIST or other NMI (*e.g.,* VSL, NPL) and may be used for traceability purposes.

3.3 *Dual Method Certification* means a process in which the gravimetric value is independently confirmed by a measured value.

3.4 *EPA Protocol Gas means* a calibration or reference gas required for emissions monitoring directly traceable to NIST or

other accepted NMI reference gas standards, prepared following the EPA Traceability Protocol

3.5 *EPA Traceable Protocol for Assay and Calibration Gas Standards or commonly referred to as the ''EPA Traceability Protocol''* means the document The protocol allows producers of these standards, users of gaseous standards, and other analytical laboratories to establish traceability of EPA Protocol Gases to gaseous reference standards produced by the National Institute of Standards and Technology (NIST).

3.6 *Gas Calibration Cylinder means* a refillable cylinder that meets the applicable DOT/TC specifications for high pressure cylinders. The cylinders shall be permanently stamped with a unique value.

3.7 *Gas Manufacturer Alternative Certified Standards or GMACS* means a gas that has been prepared according to this procedure and serves as a functional substitute for an EPA Protocol Gas where EPA Protocol gases are not available.

3.8 *Gas Manufacturer Intermediate Standard* means a gas reference standard made by a gas supplier and certified according to the U.S. EPA protocol rules for GMISs. For the purpose of this Appendix, GMISs may be assayed against a GMPS.

3.9 *Gas Manufacturer Primary Standards or GMPS* means a reference gas standard prepared and certified by the SGM that serves as a functional substitute for the reference gas standards established by, but not yet available from NIST or other accepted NMI and required by the EPA Traceability Protocol to produce EPA Protocol gases.

3.10 *Gravimetry* means the quantitative measurement of an analyte by weight.

3.11 *NIST* means the National Institute of Standards and Technology, located in Gaithersburg, Maryland.

3.12 *NIST Traceable Reference Material or NTRM* means is a reference material produced by a commercial supplier with a well-defined traceability linkage to NIST and named by NIST procedures, on a batch rather than individual basis. This linkage is established via criteria and protocols defined by NIST that are tailored to meet the needs of the metrological community to be served.

3.13 *Primary Reference Materials or PRM* means a mixture composition is verified against VSL's own primary standard gas mixtures to confirm the assigned value.

3.14 *Protocol Gas* means a calibration or reference gas required for emissions monitoring traceable to NIST or other accepted NMI, prepared following the EPA Traceability Protocol.

3.15 *Research Gas Mixture or RGMs* means a reference material produced by a commercial supplier certified by NIST on an individual basis, often using non routine procedures, are called Research Gas Mixtures (RGMs), and may be used for traceability purposes.

3.16 *Specialty Gas Manufacturer or SGM* means an organization that prepares and certified gas calibration gas mixtures.

3.17 *International System of Units or SI* means the standards for international measurement and are comprised of length (meter), time (second), amount of substance (mole), electric current (ampere), temperature (kelvin), luminous intensity (candela), and mass (kilogram).

3.18 *Standard Reference Material or SRM* means a material or substance issued by NIST that meets NIST-specific certification criteria and is issues with that with a certificate or certificate of analysis that reports the results of its characterizations and provides information regarding the appropriate use(s) of the material.

3.19 *Uncertainty* means the expression of the statistical dispersion of the values attributed to a measured quantity. For the purpose of this appendix, uncertainty is calculated using the root sum square of all uncertainty budget items associated with each procedure at k=2 (*i.e.,* approximately 95 confidence).

3.20 VSL means Van Swinden National Lab, located in Delft, Netherlands.

4.0 Interferences—Reserved

5.0 Safety

The procedures required under this appendix may involve hazardous materials, operations, and equipment. This procedure may not address all of the safety problems associated with these procedures. You as the facility or operator must establish appropriate safety and health practices and determine the applicable regulatory limitations prior to performing these procedures. You should consult instrument operation manuals, material safety data sheets, compressed gas safety requirements, and other Occupational Safety and Health Administration regulations for specific precautions to be taken.

6.0 Equipment and Supplies

This procedure is not prescriptive on the type of equipment or the supplies necessary for the preparation of GMPS and GMACS gaseous cylinder standards, however SGM must use the appropriate equipment and supplies necessary to meet the uncertainty requirements in this appendix.

7.0 Reagents and Standards—Reserved

8.0 Procedures.

The exact procedures used will depend on the gas manufacturer and the physical characteristics of the compound being prepared as a gaseous calibration standard. Any procedure is deemed appropriate so long as the criteria in section 8.1 for GMPS and section 8.2 for GMACS are met.

8.1 *Preparation and Certification of the GMPS.*

The GMPS certified value is established using the dual certification approach. A candidate GMPS cylinder is prepared gravimetrically, and its established reference value is confirmed by an independent measurement traceable to SI units as well as other appropriate reference materials. The level of agreement between the gravimetric reference value and the SI-based independent measurements along with the average value and associated, combined, expanded uncertainties serve to establish the certified reference value. If high purity reference material is not readily available for a gravimetric preparation, a user may petition the Administrator for an alternative method for preparation of a GMPS.

The procedures for the gravimetric preparation, stability evaluation, and independent verification of GMPS must meet the criteria in this section following the procedures in 8.1*(a)* through *(g).*

(a) Raw Materials

(b) GMPS Cylinder Preparation/Creation

(c) GMPS Cylinder Independent Verification

(d) GMPS Cylinder Certification

(e) GMPS Cylinder Stability

(f) GMPS Cylinder Expiration Period

(g) GMPS Documentation

8.1.1 Raw Materials. Raw materials used in the production of GMPS must be of high quality (*e.g.,* 99+% purity recommended). Additionally, because raw material purity is the largest component of uncertainty in gas gravimetry, SGMs must substantiate the purity of the raw material prior to use, either via (1) a validated certificate of analysis for the actual lot number purchased provided by the raw material vendor, or (2) a purity assay conducted by the SGM on the actual raw material to be used. The uncertainty of the raw material (U_r) assay must be included as one of the components of the total combined uncertainty for the mixture.

8.1.2 GMPS Gravimetric Cylinder Preparation/Creation. The GMPS standards shall be based on a gravimetric preparation. The gravimetric preparation shall yield an expected concentration for the target component, and with the required statistical controls in place to calculate the uncertainty of that concentration.

8.1.2.1 The scale used to generate the gravimetric reference standard must be independently calibrated over the range of target masses with ASTM E617–13 Class-1 weights on no less than a yearly basis. For such certifications, a high accuracy mass comparator (electronic or pendulum-type scale) is employed as the ''scale.'' The resolution of the scale should be sufficient to be able to calculate the overall uncertainty of any concentration derived from these steps.

8.1.2.1.1 The scale used for the gravimetric operation must be independently calibrated and traceable to NIST standards with a defined uncertainty (u_t).

8.1.2.1.2 The scale calibration must be checked before the start of each new weighing operation (*i.e.,* the day of) with a weight in the appropriate range that also meets ASTM E617–13 Class-1 requirements.

8.1.2.1.3 All material and equipment associated with the gravimetric analysis shall have or apply a procedure to estimate the uncertainty of the measurement, including but not limited to the balance(s) used (u_{ca}) standard weight (u_w).

8.1.2.1.4 The assay purity and associated material uncertainty (u_r) of the assay for each component raw material and the balance gas must be known. This purity deviation is factored into the uncertainty of the mass of each material blended into the mixture.

8.1.2.1.5 The procedures below are minimum requirements and do not speak to all of the details an SRM would do to ensure the preparation of a high-accuracy gravimetric candidate GMPS, (*e.g.,* controls for external factors that would influence scale reading accuracy buoyancy effects, moisture/dust adsorption on the cylinder

surface, and errors caused by the location of the cylinder on the scale). The SGM should develop and follow and internal standard operation procedures (SOP) for the preparation of the candidate GMPS.

8.1.2.1.6 Record the Target cylinder identification number, blend date, and balance gas on the appropriate form (see figure B–1). Additionally, record the intended component(s) to be used in the preparation for this candidate GMPS, identifying the standard type, material name (*e.g.,* Ethylene Oxide), MW (g/mol), and purity (wt%).

8.1.2.1.7 Add the components to the candidate GMPS, recording the weight of each component added.

8.1.2.1.8 GMPS Gravimetric Uncertainty. Calculate and document the gravimetric concentration (GMPS–C_g) for each component of the candidate GMPS. You must also document the combined uncertainty, expressed as the root sum of the uncertainty budget items identified, for the candidate GMPS value (GMPS–C_{gu}). Gravimetric preparation uncertainty budget items include:

(a) The purity of the raw material and the balance gas;

(b) The measured accuracy of the (electronic) balance including consideration the uncertainty of the calibration weights, the calibration uncertainty, and its linearity;

(c) The repeatability of the balance readings including errors caused by the location of the cylinder on the balance;

(d) Balance Buoyancy effects;

(e) Effects of moisture adsorption and dust on the outer surface of the cylinder;

(f) Cylinder dilutions, if any, used to prepare target concentrations, including propagated uncertainties.

8.1.3 *GMPS Independent Verification.* The certification of the candidate GMPS is based on independent measurements verifying the reference concentration of the gravimetrically prepared GMPS candidate. The independent verification must be based on a measurement approach traceable to the SI and may include the use of intrinsic NIST or accepted NMI reference materials to establish said traceability. Candidate independent verification measurement approaches include classical chemistry, spectroscopic approaches, as well as other instrumental approaches as long as adequate and appropriate SI traceability can be incorporated. The approach must be performed using NIST (or equivalent) traceable calibrations materials and using procedures that would allow the user to determine the overall uncertainty of the measurement. In some instances, a component may not be suitable to analysis using a classical approach, in those instances alternative approaches may be used do long as they (1) yield a concentration for the target com, (2) have a calculated uncertainty, (3) have traceability to the SI, and (4) documented conformity to the general metrological principles for primary methods outlined above.

8.1.3.1 *GMPS Independent Verification Measurement Uncertainty.* The cumulative uncertainty of the GMPS independent verification measurement approach is integral to the ability to assess the overall quality of the independent verification measurement. You must also document the combined uncertainty, expressed as the root sum of the uncertainty budget items identified. Ensure that all known or suspected sources of bias and imprecision have been accounted for. The following elements are examples of sources of measurement error that must be included in the overall uncertainty calculation for the GMPS independent verification measurement:

(a) The uncertainty of the certified reference solution (the traceability source);

(b) Any propagated uncertainties through serial dilutions;

(c) The errors in volumetric sampling of the candidate GMPS mixture;

(d) The uncertainty of the instrument calibration curve (least squares fit and residual);

(e) The bias or error associated with any measurement interferences;

(f) The repeatability of replicate aliquot injections from the same sample;

(g) The repeatability of replicate samples of the mixture;

(h) Any external factors influencing sampling or instrument accuracy;

(i) The uncertainty of measured volumetric gas flows;

(j) The bias or uncertainty associated with quantitative gas flow delivery;

(k) The error associated with instrumental measurement analyzers;

(l) Replicate measurement instrument error and precision.

8.1.4 GMPS Certification. The candidate GMPS certified value is based on three factors:

(a) The relative agreement between the gravimetric reference value and the independent, measured value of the gravimetrically-prepared GMPS candidate;

(b) The combined, expanded uncertainty (k=2) of the gravimetric value and independently measured concentrations values;

(c) The average of the independently measured concentrations values.

8.1.4.1 GMPS Relative Agreement. Calculate the relative agreement according to equation B–1, expressed as Relative Percent Difference (RPD) between the gravimetric concentration (GMPS–C_g) the independently measured concentrations (GMPS–C_a). The results of these two analyses must agree within 4.0 percent (%).

$$RPD = \frac{\text{GMPS-}C_g - \text{GMPS-}C_a}{\left(\frac{\text{GMPS-}C_g + \text{GMPS-}C_a}{2}\right)} \qquad \text{Eq. B1}$$

8.1.4.2 GMPS Combined, Expanded Uncertainty. Determine the individual uncertainties for the gravimetric approach (GMPS–C_{ug}) and the independent measurement verification approach (GMPS–C_{ua}) according to equation B–2. Establish the GMPS combined, expanded uncertainty (GMPS–C_{uc}) as the root sum of the two individual uncertainties with a coverage factor k=2. The combined uncertainty must ≤5.0 percent (%). If these objectives are not met, the candidate GMPS is not acceptable, and must not be used.

$$\text{GMPS-}C_{ug} \text{ or GMPS-}C_{ua} = \sqrt{u_1^2 + u_2^2 + \cdots + u_i^2} \qquad \text{Eq. B2}$$

8.1.4.3 GMPS Certified Concentration Value. If the GMPS meets the Relative Agreement criteria in section 8.1.5.3 and the combined, expanded uncertainty criteria in section 8.1.5.4, the GMPS is valid. The GMPS certified value (GMPS–C_C) is based on the independently measurement concentration (GMPS–C_a). The certification date is the date of the last confirmatory measurement.

8.1.4.4 An SGMs may propose to Administrator an alternative acceptance values for section 8.1.5.1 or 8.1.5.2 for those components that are unable to meet the documented criteria. These proposals must include sufficient documentation that the objectives are unreasonable for a given component and concentrations.

8.1.5 GMPS Stability Testing. The SGM must test and document mixture stability of the GMPS to assure that the mixture stays within claimed accuracy bounds for the entire claimed expiration period. Alternatively, once a preparation process has been developed, the SGM can perform a stability study consisting not less than three cylinders prepared using the defined process and at the concentration(s) defined by the process. Once the stability study cylinders have demonstrated acceptable stability for

the minimum expiration period (6-months), additional GMPS cylinders can be prepared under identical process conditions.

8.1.5.1 The SGM may select the sampling frequency based on the targeted expiration period, the gas consumed in the analysis and expected component behavior. Stability testing data must consist of at least:

(a) Five discrete samplings of the retained mixture for an expiration period of 6-months to 1-year;

(b) Ten discrete samplings for an expiration period of 1–3 years; and

(c) Twenty for any period greater than 3 years.

8.1.5.2 Stability testing must be conducted for each cylinder size/type and at a similar concentration as the candidate GMPS. Stability analyses must be performed using methods that assure consistent results can be achieved. If instrumental analysis using a gas standard is employed, use of a GMPS standard is highly recommended. In the absence of a certified GMPS, stability testing must be conducted using the same independent verification measurement procedures and methodology used in section 8.1.4, or using another known-to-be-stable gas standard containing the target component in a similar concentration range.

8.1.5.3 Stability testing data must not show any upward or downward trends that would cause the mixture to become out of specification prior to the claimed expiration period.

8.1.6 GMPS Expiration Period. The expiration period for the GMPS mixture based must be based on the empirical stability test data. The expiration periods for reactive gases must not exceed the length of the stability test, however for non-reactive gases you may forecast an expiration period not to exceed two times the actual stability testing duration. The maximum expiration period for a GMPS is time span from the date of preparation to the date of the last/most recent stability study may not be less than 6-months. Provided that acceptable stability is observed, the maximum expiration period may be extended by retaining the stability study cylinders and performing additional analyses.

8.1.7 GMPS Documentation. You must document the preparation of the GMPS through the appropriate record keeping and document the certification of a GMPS. The information is section 8.1.8.1 and 8.1.8.2 must be maintained as a record by the SGM for the purpose of maintaining traceability and to verify the preparation. The information in section 8.1.8.3 must be documented and maintained by the SGM. This documentation and the records of the preparation and certification must be made available upon request by the appropriate delegated authority.

8.1.7.1 The following information for the gravimetric preparation information of the GMPS must be documented and maintained as a record. This record should include but is not limited to the: blend date, gravimetric concentration, gravimetric concentration uncertainties as a percentage and absolute, reference material information and purity, scale ID, scale accuracy, and calculated gravimetric uncertainties associated with material, balance, and environmental effects. You must include sufficient information that will allow a 3rd party to recalculate the prepared concentration and expanded uncertainties.

8.1.7.2 The following information for the analytical verification of the GMPS must be recorded and maintained as a record. This record should include the confirming methodology and any associated SOPs, confirming concentration(s), instrumentation used, calibration standards used and associated COAs, calibration curve data, replicate analysis calculated, and expanded uncertainties.

8.1.7.3 The following information must be documented for inclusion on the COA for the GMACS.

(a) Manufacturer's company name and address of the producing location

(b) Manufacturer's part number for the GMPS, lot number, and/or production record.

(c) Cylinder number, cylinder type, cylinder preparation ID, moisture dew point and cylinder pressure.

(d) Certification date and claimed expiration date.

(e) GMPS component(s) name, final certified concentration(s) (GMPS–C_c), and balance gas.

(f) Gravimetric value and uncertainty

(g)Verification value and uncertainty

(h) GMPS final certified value and uncertainty absolute as a percentage (GMPS–C_u)

8.2 Preparation and Certification of the GMACS. The preparation and certification of the candidate GMACS is also based on the independent verification of the gravimetrically prepared reference value. However, the independent verification utilizes the GMPS to perform the independent verification. This is accomplished by following the procedures in section 2.1 and 2.2 of the EPA Traceability Protocol, using the GMPS as the certified reference material. The measured value of the independent verification following the EPA Traceability Protocol procedures also establishes the certified reference value, providing the relative agreement performance criteria are met.

8.2.1 GMACS Gravimetric Cylinder Preparation/Creation. The gravimetric preparation of the GMACS is identical to the procedures used to gravimetrically prepare the GMPS. You must maintain the same information required for the gravimetric preparation of GMPS, as found in section 8.1.8.1 for GMACS, as a record.

8.2.2 GMACS Independent Verification and Certification. The candidate GMACS independent verification of the gravimetrically prepared reference value is contingent on the SGM following the procedures in sections 2.1 and 2.2 of the EPA Traceability Protocol. In addition, the EtO candidate GMACS certified reference value and associated expanded uncertainty is based on the EPA Traceability Protocol measured value. This is contingent upon the gravimetric and measured values meeting the relative agreement performance criteria established in section 8.1.5.3 and the uncertainty criteria established in section 8.1.5.4. Gas Manufacturers Intermediate Standards (GMIS) can be prepared by direct comparison to a GMPS that has been prepared and certified according to section 2.1.3.1 and 2.2 of the EPA Traceability Protocol. The tagged value of the GMACS must be based on the EPA Traceability Protocol measured value as long as the performance criteria in sections 12.1 and 12.2 are met.

8.2.3 GMACS Stability Testing. The SGM must test and document the stability of the GMACS to assure that the mixture stays within claimed certified bounds for the entire claimed expiration period. Use the procedures in section 8.1.6 to assess stability. The GMACS must also meet the requirements in section 2.1.5.2 of the EPA Traceability Protocol.

8.2.4 GMACS Expiration Date. The certification period of the GMACS shall be based on the documented stability tests of the GMPS in section 8.1.6. The expiration date shall be based on the certification date, plus the certification period plus one day. There is not a maximum period of expiration; however, expiration periods must not be less than six months.

8.2.5 GMACS Documentation You must document and maintain the same information required for the analytical verification of the GMPS, as found in section 8.1.8 for GMACS, as a record. The records of the preparation and certification must be made available upon request by the appropriate delegated authority.

8.2.6 GMACS Certificate of Analysis (COA). You must provide comprehensive documentation of the GMPS and GMACS development process in the form of a GMACS Certificate of Analysis (COA) that accompanies each commercially distributed GMACS. As a minimum, the COA must contain the following information:

(a) Identification of the gas as a Gas Manufacturer Alternative Certified Standard;

(b) The cylinder number;

(c) The certified concentration of the GMACS;

(d) The combined expanded uncertainty (k=2) of the GMACS reference value (both absolute and relative);

(e) The expiration date;

(f) The reference materials or standards used (*i.e.,* GMPS and GMIS);

(g) The same information (cylinder number, certified concentration, uncertainties, expiration dates, etc. for these cylinders);

(h) The gravimetric and independent measured verification reference concentration values and associated uncertainties for each GMPS used;

(i) Associated measurement principles and uncertainties;

(j) Any additional information stipulated by the EPA Traceability Protocol;

(k) Any comments/special instructions.

The SGM GMACS provider is encouraged to include additional relevant information to the COA, as appropriate. An example GMACS COA can be found in section 14 of this appendix.

9.0 Quality Control—Reserved

10.0 Calibration and Standardization

There is a myriad of instrumental and mechanical techniques used in the

performance of this Appendix B. When reference methods are used, you must follow the calibration requirements of those methods and as defined in this appendix. For all other approaches, it is recommended to develop internal SOPs and develop.

11.0 Calculations and Data Analysis—Reserved

12.0 Method Performance

12.1 GMPS/GMACS Relative Agreement. As part of the certification/verification procedures for the candidate GMPS and GMACS, the relative agreement between the gravimetrically prepared reference value and the independently measured verification value must agree within 4.0 percent (%).

12.2 GMACS/GMPS Uncertainty. Final certification of the GMPS and GMACS reference concentrations must meet the combined expanded uncertainty (k=2) of ≤5.0 percent (%).

13.0 Pollution Prevention—Reserved

14.0 Waste Management—Reserved

15.0 Bibliography

1. EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards, Office of Research and Development, National Risk Management Research Laboratory, May 2012, EPA 600/R–12/531. *https://www.epa.gov/air-research/epa-traceability-protocol-assay-and-certification-gaseous-calibration-standards.*

2. EPA Alternative Method 114, Approval of Alternative Method for preparation of HCl Gas Standards for PS–18 and Procedure 6, February 22, 2016, *https://www.epa.gov/sites/default/files/2020-08/documents/alt114.pdf.*

3. Evaluation of Measurement Data—Guide to the Expression of Uncertainty in Measurement, JCGM 100:2008, *https://www.bipm.org/documents/20126/2071204/JCGM_100_2008_E.pdf/cb0ef43f-baa5-11cf-3f85-4dcd86f77bd6.*

16.0 Tables and Figures

Figure B–1 Example Gravimetric Preparation Sheet for GMPS and GMACS

BILLING CODE 6560–50–P

General Information

Project	Operator	Blend Date	Cylinder Number
Phase	Valve Connection	Blend Pressure	Headspace

Component Parameters

	Component 1	Component 2	Component 3	Component 4	Component 5
Material Name					
Material molecular weight (g/mol)					
Dilution Standard or Pure Cylinder Number					
Lot Number					
Dilution Standard Weight Concentration or Pure Weight % Assay (wt%)					
Dilution Standard Weight Accuracy, relative or +/- weight% uncertainty (wt%)					
Dilution Standard or Pure Weight (g)					
Mechanical Effects - u_m (g)					
Scale Capacity Selection (g)					
Scale Calibration Uncertainty - u_{sca} (g)					
Scale Accuracy - u_s (g)					
Weight Standard - u_{std} (g)					
Material Weight Added (g)					
Material Uncertainty - u_c (g)					
Total Weight Uncertainty (g)					
Additional Weight Uncertainty (g)					

Dilution Standard or Cross Contaminant Additions

Contributing Component #					
Weight Added (g)					
Uncertainty (g)					
Contributing Component #					
Weight Added (g)					
Uncertainty (g)					

Totals Calculations

Total Weight from all additions (g)					
Total moles					

Concentrations and Accuracy Calculations

Weight Concentration (%)					
Weight Accuracy Relative (%)					
Mole Concentration (%)					
Standard Uncertainty - u_i (%)					

Figure B–2 Apparatus for the assay of the GMACs

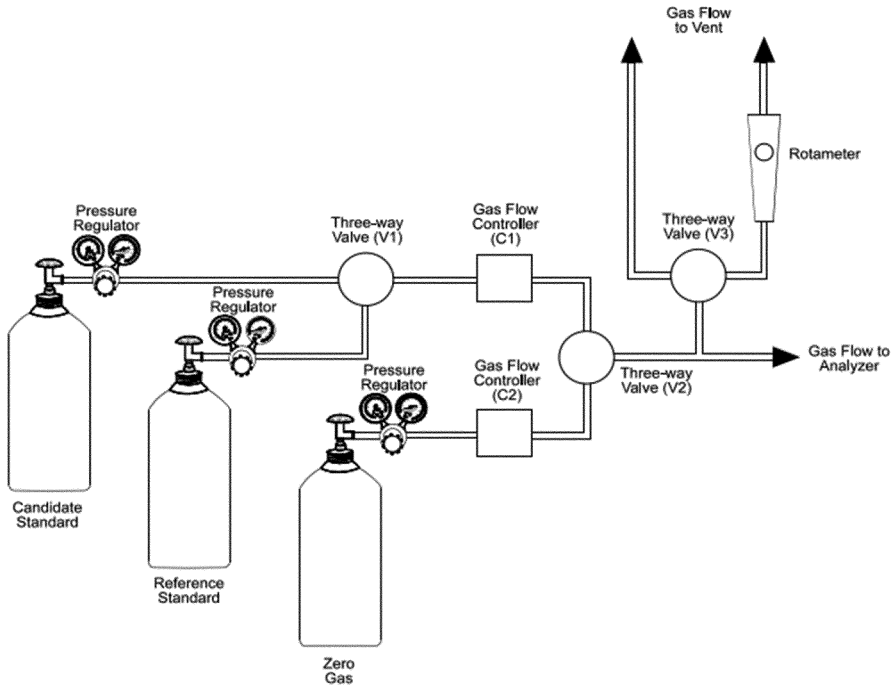
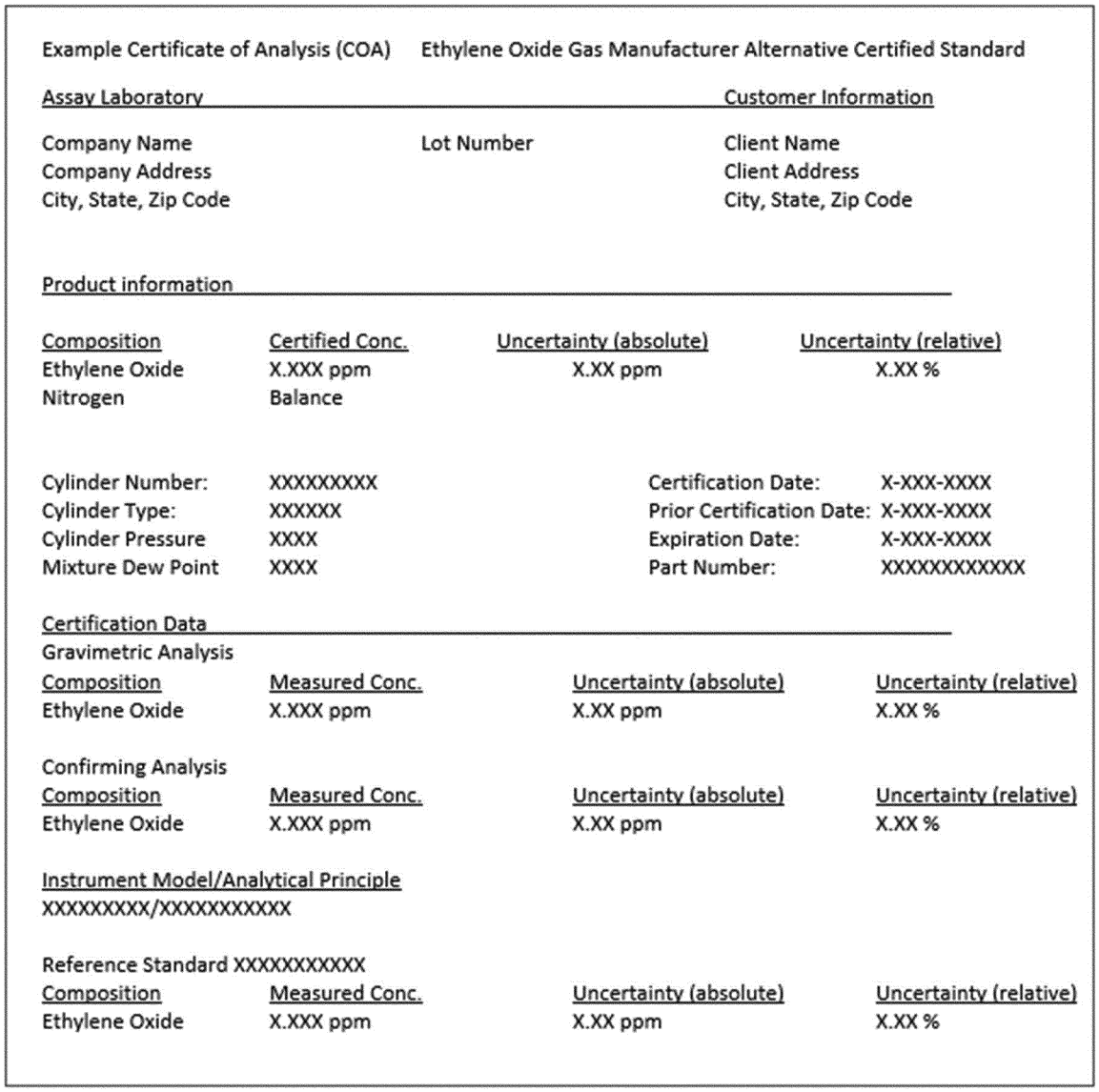


Figure B–3 Examples COA



Example Certificate of Analysis (COA) Ethylene Oxide Gas Manufacturer Alternative Certified Standard

Assay Laboratory — Customer Information

Company Name — Lot Number — Client Name
Company Address — Client Address
City, State, Zip Code — City, State, Zip Code

Product information

Composition	Certified Conc.	Uncertainty (absolute)	Uncertainty (relative)
Ethylene Oxide	X.XXX ppm	X.XX ppm	X.XX %
Nitrogen	Balance		

Cylinder Number:	XXXXXXXXX	Certification Date:	X-XXX-XXXX
Cylinder Type:	XXXXXX	Prior Certification Date:	X-XXX-XXXX
Cylinder Pressure	XXXX	Expiration Date:	X-XXX-XXXX
Mixture Dew Point	XXXX	Part Number:	XXXXXXXXXXXX

Certification Data

Gravimetric Analysis

Composition	Measured Conc.	Uncertainty (absolute)	Uncertainty (relative)
Ethylene Oxide	X.XXX ppm	X.XX ppm	X.XX %

Confirming Analysis

Composition	Measured Conc.	Uncertainty (absolute)	Uncertainty (relative)
Ethylene Oxide	X.XXX ppm	X.XX ppm	X.XX %

Instrument Model/Analytical Principle
XXXXXXXXX/XXXXXXXXXXX

Reference Standard XXXXXXXXXXX

Composition	Measured Conc.	Uncertainty (absolute)	Uncertainty (relative)
Ethylene Oxide	X.XXX ppm	X.XX ppm	X.XX %

BILLING CODE 6560–50–C

■ 3. Appendix F to part 60 is amended by adding Procedure 7 to read as follows:

Appendix F to Part 60—Quality Assurance Procedures

* * * * *

Procedure 7. Quality Assurance Requirements for Gaseous Ethylene Exide (ETO) Continuous Emission Monitoring Systems Used for Compliance Determination

1.0 Applicability and Principle

1.1 Applicability. Procedure 7 is used to evaluate the effectiveness of quality control (QC) and quality assurance (QA) procedures and to evaluate the quality of data produced by any ethylene oxide (EtO) gas, CAS: 75–21–8, continuous emission monitoring system (CEMS) that is used for determining compliance with emission standards for EtO on a continuous basis as specified in an applicable permit or regulation.

1.1.1 This procedure specifies the minimum QA requirements necessary for the control and assessment of the quality of CEMS data submitted to the Environmental Protection Agency (EPA) or a delegated authority. If you are responsible for one or more CEMS used for EtO compliance monitoring you must meet these minimum requirements and you are encouraged to develop and implement a more extensive QA program or to continue such programs where they already exist.

1.1.2 Data collected as a result of QA and quality control (QC) measures required in this procedure are to be submitted to the EPA or the delegated authority in accordance with the applicable regulation or permit. These data are to be used by both the delegated authority and you, as the CEMS operator, in assessing the effectiveness of the CEMS QC and QA procedures in the maintenance of acceptable CEMS operation and valid emission data.

1.2 Principle

1.2.1 The QA procedures consist of two distinct and equally important functions. One function is the assessment of the quality of the CEMS data by estimating accuracy. The other function is the control and improvement of the quality of the CEMS data by implementing QC policies and corrective actions. These two functions form an iterative control loop. When the assessment function indicates that the data quality is inadequate, the control effort must be increased until the data quality is acceptable. In order to provide uniformity in the assessment and reporting of data quality, this procedure specifies the assessment procedures to evaluate response drift and accuracy. The procedures specified are based on Performance Specification 19 (PS–19) in appendix B to this part.

Note 1 to section 1.0: Because the control and corrective action function encompasses a variety of policies, specifications, standards and corrective measures, this procedure treats QC requirements in general terms to allow you, as source owner or operator to develop the most effective and efficient QC system for your circumstances.

2.0 Definitions

See PS–19 in appendix B to this part for the primary definitions used in this Procedure.

3.0 QC Requirements

3.1 You, as a source owner or operator, must develop and implement a QC program. At a minimum, each QC program must include written procedures and/or manufacturer's information which should describe in detail, complete, step-by-step procedures and operations for each of the following activities:

(a) Calibration Drift (CD) checks of CEMS;

(b) CD determination and adjustment of CEMS;

(c) Routine and preventative maintenance of CEMS (including spare parts inventory);

(d) Data recording, calculations, and reporting;

(e) Accuracy audit procedures for CEMS including reference method(s); and

(f) Program of corrective action for malfunctioning CEMS.

3.2 These written procedures must be kept on site and available for inspection by the delegated authority. As described in section 5.4, whenever excessive inaccuracies occur for two consecutive quarters, you must revise the current written procedures, or modify or replace the CEMS to correct the deficiency causing the excessive inaccuracies.

4.0 Daily Data Quality Requirements and Measurement Standardization Procedures

4.1 CD Assessment. An upscale gas, used to meet a requirement in this section must be a gas meeting the requirements in section 7.1 of PS–19 of appendix B to this part.

4.1.1 CD Requirement. Consistent with § 60.13(d) and with § 63.8(c) of this chapter, you, as source owners or operators of CEMS must check, record, and quantify the CD at two levels, using a zero gas and high-level gas at least once daily (approximately every 24 hours). Perform the CD check in accordance with the procedure in the applicable performance specification (*e.g.,* section 11.3 of PS–19 in appendix B to this part). The daily zero- and high-level CD must not exceed two times the drift limits specified in the applicable performance specification (*e.g.,* section 13.2 of PS–19 in appendix B to this part.)

4.1.2 Recording Requirement for CD Corrective action. Corrective actions taken to bring a CEMS back in control after exceeding a CD limit must be recorded and reported with the associated CEMS data. Reporting of a corrective action must include the unadjusted concentration measured prior to resetting the calibration and the adjusted value after resetting the calibration to bring the CEMS back into control.

4.1.3 Dynamic Spiking Option for high-level CD. You have the option to conduct a daily dynamic spiking procedure found in section 11.5.8 of PS–19 of appendix B to this part in lieu of the daily high-level CD check. If this option is selected, the daily zero CD check is still required.

4.1.4 Out of Control Criteria for Excessive CD. Consistent with § 63.8(c)(7)(i)(A) of this chapter, an EtO CEMS is out of control if the zero or high-level CD exceeds two times the applicable CD specification in the applicable performance specification or in the relevant standard. When a CEMS is out of control, you as owner or operator of the affected source must take the necessary corrective actions and repeat the tests that caused the system to go out of control (in this case, the failed CD check) until the applicable performance requirements are met.

4.1.5 Additional Quality Assurance for Data Above Span. This procedure must be used when required by an applicable regulation and may be used when significant data above span are being collected. Furthermore, the terms of this procedure do not apply to the extent that alternate terms are otherwise specified in an applicable rule or permit.

4.1.5.1 Any time the average measured concentration of EtO exceeds 200 percent of the span value for two consecutive one-hour averages, conduct the following 'above span' CEMS response check.

4.1.5.1.1 Within a period of 24 hours (before or after) of the 'above span' period, introduce a higher, 'above span' EtO reference gas standard to the CEMS. Use 'above span' reference gas that meets the requirements of section 7.0 of PS–19 in appendix B to this part and target a concentration level between 75 and 125 percent of the highest hourly concentration measured during the period of measurements above span or 5 ppmv whichever is greater.

4.1.5.1.2 Introduce the reference gas at the probe for extractive CEMS.

4.1.5.1.3 At no time may the 'above span' concentration exceed the analyzer full-scale range.

4.1.5.2 Record and report the results of this procedure as you would for a daily calibration. The 'above span' response check is successful if the value measured by the CEMS is within 20 percent of the certified value of the reference gas.

4.1.5.3 If the 'above span' response check is conducted during the period when measured emissions are above span and there is a failure to collect at least one data point in an hour due to the response check duration, then determine the emissions average for that missed hour as the average of hourly averages for the hour preceding the missed hour and the hour following the missed hour.

4.1.5.4 In the event that the 'above span' response check is not successful (*i.e.,* the CEMS measured value is not within 20 percent of the certified value of the reference gas), then you must normalize the one-hour average stack gas values measured above the span during the 24-hour period preceding or following the 'above span' response check for reporting based on the CEMS response to the reference gas as shown in Eq. 7–1:

Eq. 7-1

$$\text{Normalized stack gas result} = \frac{\textit{Certified reference gas value}}{\textit{Measured value of reference gas}} \; x \; \textit{Measured stack gas result}$$

4.2 Out of Control Period Duration for Daily Assessments. The beginning of the out-of-control period is the hour in which the owner or operator conducts a daily performance check (*e.g.,* calibration drift) that indicates an exceedance of the performance requirements established under this procedure. The end of the out-of-control period is the completion of daily assessment of the same type following corrective actions, which shows that the applicable performance requirements have been met.

4.3 CEMS Data Status During Out-of-Control Period. During the period the CEMS is out-of- control, the CEMS data may not be used in calculating compliance with an emissions limit nor be counted towards meeting minimum data availability as required and described in the applicable regulation or permit.

5.0 Data Accuracy Assessment

You must audit your CEMS for the accuracy of EtO measurement on a regular basis at the frequency described in this section, unless otherwise specified in an applicable regulation or permit. Quarterly audits are performed at least once each calendar quarter. Successive quarterly audits, to the extent practicable, shall occur no closer than 2 months apart. Annual audits are performed at least once every four consecutive calendar quarters.

5.1 Concentration Accuracy Auditing Requirements. Unless otherwise specified in an applicable regulation or permit, you must audit the EtO measurement accuracy of each CEMS at least once each calendar quarter, except in the case where the affected facility is off-line (does not operate). In that case, the audit must be performed as soon as is practicable in the quarter in which the unit recommences operation. Successive quarterly audits must, to the extent practicable, be performed no less than 2 months apart. The

accuracy audits shall be conducted as follows:

5.1.1 Relative Accuracy Test Audit (RATA). A RATA must be conducted at least once every four calendar quarters, except as otherwise noted in sections 5.1.5 or 5.5 of this procedure. Perform the RATA as described in section 11.6 of PS–19 in appendix B to this part. If the EtO concentration measured by the RM during a RATA (in ppmv or other units of the standard) is less than or equal to 20 percent of the concentration equivalent to the applicable emission standard, you must perform a Cylinder Gas Audit (CGA) or a Dynamic Spike Audit (DSA) for at least one subsequent (one of the following three) quarterly accuracy audits.

5.1.2 Quarterly Relative Accuracy Audit (RAA). A quarterly RAA may be conducted as an option to conducting a RATA in three of four calendar quarters, but in no more than three quarters in succession. To conduct an RAA, follow the test procedures in section 11.6 of PS–19 in appendix B to this part, except that only three test runs are required. The difference between the mean of the RM values and the mean of the CEMS responses relative to the mean of the values (or alternatively the emission standard) is used to assess the accuracy of the CEMS. Calculate the RAA results as described in section 6.2. As an alternative to an RAA, a cylinder gas audit or a dynamic spiking audit may be conducted.

5.1.3 Cylinder Gas Audit. A quarterly CGA may be conducted as an option to conducting a RATA in three of four calendar quarters, but in no more than three consecutive quarters. To perform a CGA, challenge the CEMS with a zero-level and two upscale level audit gases of known concentrations within the following ranges:

Audit point	Audit range
1 (Mid-Level)	50 to 60% of span value.
2 (High-Level)	80 to 100% of span value.

5.1.3.1 Inject each of the three audit gases (zero and two upscale) three times each for a total of nine injections. Inject the gases so that the entire measurement system is challenged. Do not inject the same gas concentration twice in succession.

5.1.3.2 Use EtO audit gases that meet the requirements of section 7 of PS–19 in appendix B to this part.

5.2.3.3 Calculate results as described in section 6.3.

5.1.4 Dynamic Spiking Audit. A quarterly DSA may be conducted as an option to conducting a RATA in three of four calendar quarters, but in no more than three quarters in succession.

5.1.4.1 To conduct a DSA, you must challenge the entire EtO CEMS with a zero gas in accordance with the procedure in section 11.8 of PS–19 in appendix B of this part. You must also conduct the DS procedure as described in appendix A to PS–19 of appendix B to this part. You must conduct three spike injections with each of two upscale level audit gases. The upscale level gases must meet the requirements of section 7 of PS–19 in appendix B to this part and must be chosen to yield concentrations at the analyzer of 50 to 60 percent of span and 80 to 100 percent of span. Do not inject the same spike gas concentration twice in succession.

5.1.4.2 Calculate results as described in section 6.4. To determine CEMS accuracy, you must calculate the dynamic spiking error (DSE) for each of the two upscale audit gases using equation A5 in appendix A to PS–19 and equation 7–3 in section 6.4 of this Procedure.

5.1.5 Other Alternative Quarterly Audits. Other alternative audit procedures, as approved by the Administrator, may be used for three of four calendar quarters.

5.2 Out of Control Criteria for Excessive Audit Inaccuracy. If the results of the RATA, RAA, CGA, or DSA do not meet the applicable performance criteria in section 5.2.4, the CEMS is out-of-control. If the CEMS is out-of-control, take necessary corrective action to eliminate the problem. Following corrective action, the CEMS must pass a test of the same type that resulted in the out-of-control period to determine if the CEMS is operating within the specifications (*e.g.,* a RATA must always follow an out-of-control period resulting from a RATA).

5.2.1 If the audit results show the CEMS to be out-of-control, you must report both the results of the audit showing the CEMS to be out-of-control and the results of the audit following corrective action showing the CEMS to be operating within specifications.

5.2.2 Out-Of-Control Period Duration for Excessive Audit Inaccuracy. The beginning of the out-of-control period is the time corresponding to the completion of the sampling for the failed RATA, RAA, CGA or DSA. The end of the out-of-control period is the time corresponding to the completion of the sampling of the subsequent successful audit.

5.2.3 CEMS Data Status During Out-Of-Control Period. During the period the CEMS is out-of- control, the CEMS data may not be used in calculating emission compliance nor be counted towards meeting minimum data availability as required and described in the applicable regulation or permit.

5.2.4 Criteria for Excessive Quarterly and Yearly Audit Inaccuracy. Unless specified otherwise in the applicable regulation or permit, the criteria for excessive inaccuracy are:

5.2.4.1 For the RATA, the CEMS must meet the RA specifications in section 13.4 of PS–19 in appendix B to this part.

5.2.4.2 For the CGA, the accuracy must not exceed 10.0 percent of the span value at the zero gas and the mid- and high-level reference gas concentrations.

5.2.4.3 For the RAA, the RA must not exceed 20.0 percent of the RMavg as calculated using equation 7–2 in section 6.2 of this procedure whether calculated in units of EtO concentration or in units of the emission standard. In cases where the RA is calculated on a concentration (ppbv) basis, if the average EtO concentration measured by the RM during the test is less than 75 percent of the EtO concentration equivalent to the applicable standard, you may substitute the equivalent emission standard value (in ppbw) in the denominator of equation 7–2 in the place of RM_{avg} and the result of this alternative calculation of RA must not exceed 15.0 percent.

5.2.4.4 For DSA, the accuracy must not exceed 5.0 percent of the span value at the zero gas and the mid- and high-level reference gas concentrations or 20.0 percent of the applicable emission standard, whichever is greater.

5.3 Criteria for Acceptable QC Procedures. Repeated excessive inaccuracies (*i.e.,* out-of-control conditions resulting from the quarterly or yearly audits) indicate that the QC procedures are inadequate or that the CEMS is incapable of providing quality data. Therefore, whenever excessive inaccuracies occur for two consecutive quarters, you must revise the QC procedures (see section 3.0) or modify or replace the CEMS.

5.4 Criteria for Optional QA Test Frequency. If all the quality criteria are met in sections 4 and 5 of this procedure, the CEMS is in-control.

5.5.1 Unless otherwise specified in an applicable rule or permit, if the CEMS is in-control and if your source emits ≤75 percent of the EtO emission limit for each averaging period as specified in the relevant standard for eight consecutive quarters that include a minimum of two RATAs, you may revise your auditing procedures to use CGA, RAA or DSA each quarter for seven subsequent quarters following a RATA.

5.5.2 You must perform at least one RATA that meets the acceptance criteria every 2 years.

5.5.3 If you fail a RATA, RAA, CGA, or DSA, then the audit schedule in section 5.2 must be followed until the audit results meet the criteria in section 5.3.4 to start requalifying for the optional QA test frequency in section 5.5.

6.0 Calculations for CEMS Data Accuracy

6.1 RATA RA Calculation. Follow equations 9 through 14 in section 12 of PS–19 in appendix B to this part to calculate the RA for the RATA. The RATA must be calculated either in units of the applicable emission standard or in concentration units (ppbv).

6.2 RAA Accuracy Calculation. Use equation 7–2 to calculate the accuracy for the RAA. The RA may be calculated in concentration units (ppmv) or in the units of the applicable emission standard.

$$RA = \frac{MN_{avg} - RM_{avg}}{RM_{avg}} \times 100 \qquad \text{Eq. 7-2}$$

Where:

RA = Accuracy of the CEMS (percent)

MN_{avg} = Average measured CEMS response during the audit in units of applicable standard or appropriate concentration.

RM_{avg} = Average reference method value in units of applicable standard or appropriate concentration.

6.3 CGA Accuracy Calculation. For each gas concentration, determine the average of the three CEMS responses and subtract the average response from the audit gas value. For extractive CEMS, calculate the ME at each gas level using equation 3A in section 12.3 of PS–19 of appendix B to this part.

6.4 DSA Accuracy Calculation. DSA accuracy is calculated as a percent of span. To calculate the DSA accuracy for each upscale spike concentration, first calculate the DSE using equation A5 in appendix A of PS–19 in appendix B to this part. Then use equation 7–3 to calculate the average DSA accuracy for each upscale spike concentration. To calculate DSA accuracy at the zero level, use equation 3A in section 12.3 of PS–19 in appendix B to this part.

$$\text{DSA Accuracy} = \frac{\sum_1^3 \left[\frac{|DSEi|}{S}\right]}{3} x100 \qquad \text{Eq. 7-3}$$

7.0 Reporting Requirements

At the reporting interval specified in the applicable regulation or permit, report for each CEMS the quarterly and annual accuracy audit results from section 6 and the daily assessment results from section 4. Unless otherwise specified in the applicable regulation or permit, include all data sheets, calculations, CEMS data records (*i.e.,* charts, records of CEMS responses), reference gas certifications and reference method results necessary to confirm that the performance of the CEMS met the performance specifications.

7.1 Unless otherwise specified in the applicable regulations or permit, report the daily assessments (CD and beam intensity) and accuracy audit information at the interval for emissions reporting required under the applicable regulations or permits.

7.1.1 At a minimum, the daily assessments and accuracy audit information reporting must contain the following information:

a. Company name and address.

b. Identification and location of monitors in the CEMS.

c. Manufacturer and model number of each monitor in the CEMS.

d. Assessment of CEMS data accuracy and date of assessment as determined by a RATA, RAA, CGA or DSA described in section 5 including:

i. The RA for the RATA;

ii. The accuracy for the CGA, RAA, or DSA;

iii. The RM results, the reference gas certified values;

iv. The CEMS responses;

v. The calculation results as defined in section 6; and

vi. Results from the performance audit samples described in section 5 and the applicable RMs.

e. Summary of all out-of-control periods including corrective actions taken when CEMS was determined out-of-control, as described in sections 4 and 5. 7.1.2 If the accuracy audit results show the CEMS to be out-of-control, you must report both the audit results showing the CEMS to be out-of-control and the results of the audit following corrective action showing the CEMS to be operating within specifications.

7.1.2 If the accuracy audit results show the CEMS to be out-of-control, you must report both the audit results showing the CEMS to be out-of-control and the results of the audit following corrective action showing the CEMS to be operating within specifications.

8.0 Bibliography

1. EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards, U.S. Environmental Protection Agency office of Research and Development, EPA/600/R–12/531, May 2012.

2. Method 205, ''Verification of Gas Dilution Systems for Field Instrument Calibrations,'' 40 CFR part 51, appendix M.

9.0 [Reserved]

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 4. The authority citation for part 63 continues to read as follows:

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

Subpart A—General Provisions

■ 5. Section 63.14 is amended by:

■ a. Revising paragraphs (a) and (f) and paragraph (i) introductory text;

■ b. Redesignating paragraphs (i)(88) through (119) as paragraphs (i)(89) through (120), and;

■ c. Adding new paragraph (i)(88) and note 2 to paragraph (i).

The revisions and additions read as follows:

§ 63.14 Incorporations by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the EPA must publish a document in the **Federal Register** and the material must be available to the public. All approved incorporation by reference (IBR) material is available for inspection at the EPA and at the National Archives and Records Administration (NARA). Contact the EPA at: EPA Docket Center, Public Reading Room, EPA WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC, telephone: 202–566–1744. 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.* The material may be obtained from the sources in the following paragraphs of this section.

* * * * *

(f) American Society of Mechanical Engineers (ASME), Two Park Avenue, New York, NY 10016–5990; phone: (800) 843–2763; email: *CustomerCare@asme.org;* website: *www.asme.org.*

(1) ANSI/ASME PTC 19.10–1981, Flue and Exhaust Gas Analyses [Part 10, Instruments and Apparatus], issued August 31, 1981; IBR approved for §§ 63.309(k); 63.365(b); 63.457(k); 63.772(e) and (h); 63.865(b); 63.997(e); 63.1282(d) and (g); 63.1625(b); table 5 to subpart EEEE; §§ 63.3166(a); 63.3360(e); 63.3545(a); 63.3555(a); 63.4166(a); 63.4362(a); 63.4766(a); 63.4965(a); 63.5160(d); table 4 to subpart UUUU; table 3 to subpart YYYY; §§ 63.7822(b); 63.7824(e); 63.7825(b); 63.8000(d); 63.9307(c); 63.9323(a); 63.9621(b) and (c); 63.11148(e); 63.11155(e); 63.11162(f); 63.11163(g); 63.11410(j); 63.11551(a); 63.11646(a); 63.11945; table 4 to subpart AAAAA; table 5 to subpart DDDDD; table 4 to subpart JJJJJ; table 4 to subpart KKKKK; table 4 to subpart SSSSS; tables 4 and 5 of subpart UUUUU; table 1 to subpart ZZZZZ; and table 4 to subpart JJJJJJ.

(2) [Reserved]

* * * * *

(i) ASTM International, 100 Barr Harbor Drive, P.O. Box CB700, West Conshohocken, Pennsylvania 19428–2959; phone: (800) 262–1373; website: *www.astm.org.*

* * * * *

(88) ASTM D6348–12 (Reapproved 2020), Standard Test Method for Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform (FTIR) Spectroscopy,

Approved December 1, 2020; IBR approved for § 63.365(b).

* * * * *

Note 2 to paragraph (i): Standards listed in this paragraph (i) may also be available from standards resellers including the Standards Store, *https://global.ihs.com.*

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■ 6. Subpart O is revised and republished to read as follows:

Subpart O—Ethylene Oxide Emissions Standards for Sterilization Facilities

Sec.

Subpart O—Ethylene Oxide Emissions Standards for Sterilization Facilities

§ 63.360 Applicability.

(a) You are subject to the requirements of this subpart if you own or operate a sterilization facility that has an affected source specified in paragraph (b) of this section. Table 6 to this subpart shows which parts of the General Provisions in §§ 63.1 through 63.15 apply to you.

(b) The affected sources subject to this subpart are:

(1) Each SCV at any sterilization facility;

(2) Each ARV at any sterilization facility;

(3) Each CEV at any sterilization facility;

(4) The collection of all Group 1 room air emissions at any sterilization facility; and

(5) The collection of all Group 2 room air emissions at any sterilization facility.

(c) An existing affected source is one the construction or reconstruction of which was commenced on or before April 13, 2023.

(d) A new affected source is one the construction or reconstruction of which is commenced after April 13, 2023.

(e) An SCV, ARV, or CEV is reconstructed if you meet the reconstruction criteria as defined in § 63.2, and if you commence reconstruction after April 13, 2023.

(f) This subpart does not apply to beehive fumigators.

(g) This subpart does not apply to research or laboratory facilities as defined in section 112(c)(7) of title III of the Clean Air Act Amendment of 1990.

(h) This subpart does not apply to EtO sterilization operations at stationary sources such as hospitals, doctor's offices, clinics, or other facilities whose primary purpose is to provide medical or dental services to humans or animals.

(i) If you are an owner or operator of an area source subject to this subpart, you are exempt from the obligation to obtain a permit under 40 CFR part 70 or 71, provided you are not required to obtain a permit under 40 CFR 70.3(a) or 71.3(a) for a reason other than your status as an area source under this subpart. Notwithstanding the previous sentence, you must continue to comply with the provisions of this subpart applicable to area sources.

(j) You must comply with the provisions of this subpart no later than the dates specified in paragraphs (j)(1) through (17) of this section:

(1) If you own or operate an existing affected source, you must comply with the applicable provisions of this subpart no later than the dates specified in tables 1 through 5 to this subpart, as applicable.

(2) If you own or operate a new affected source, and the initial startup of your affected source is on or before April 5, 2024, you must comply with the provisions of this subpart no later than April 5, 2024.

(3) If you own or operate a new affected source, and the initial startup is after April 5, 2024, you must comply with the provisions of this subpart upon startup of your affected source.

(4) If existing SCV, ARV, or CEV or parts of an existing collection of Group 1 or Group 2 room air emissions are replaced such that the replacement meets the definition of reconstruction in § 63.2 and the reconstruction commenced after April 13, 2023, then the existing affected source becomes a new affected source. The reconstructed source must comply with the requirements for a new affected source upon initial startup of the reconstructed source or by April 5, 2024, whichever is later.

(5) All existing SCVs at facilities that meet or exceed 1 tpy of EtO use within any consecutive 12-month period after April 7, 2025, that increase their EtO use after April 6, 2026, such that the SCV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(6) All existing SCVs at facilities that do not exceed 1 tpy of EtO use within any consecutive 12-month period after April 6, 2026, that increase their EtO use thereafter, such that the SCV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(7) All new SCVs at facilities that increase their EtO use over a year after startup such that the SCV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(8) All existing ARVs at facilities that meet or exceed 10 tpy of EtO use within any consecutive 12-month period after April 7, 2025, that increase their EtO use after April 6, 2026, such that the ARV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(9) All existing ARVs at facilities that do not exceed 10 tpy of EtO use within any consecutive 12-month period after April 6, 2026, that increase their EtO use after thereafter, such that the ARV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(10) All new ARVs at facilities that increase their EtO use over a year after startup such that the ARV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(11) All existing CEVs at facilities that do not exceed 60 tpy of EtO use within any consecutive 12-month period after April 6, 2026, that increase their EtO use thereafter, such that the CEV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(12) All new CEVs at facilities that increase their EtO use over a year after startup such that the CEV becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(13) All existing collections of Group 1 room air emissions at facilities that do not exceed 40 tpy of EtO use within any consecutive 12-month period after April 6, 2026, that increase their EtO use thereafter, such that the collection of Group 1 room air emissions becomes subject to a more stringent emission

standard, immediately upon becoming subject to the more stringent emission standard.

(14) All new Group 1 room air emissions at facilities that increase their EtO use over a year after startup such that the Group 1 room air emissions become subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(15) All existing collections of Group 2 room air emissions at facilities that meet or exceed 4 tpy of EtO use within any consecutive 12-month period after April 7, 2025, that increase their EtO use after April 6, 2026, such that the collection of Group 2 room air emissions becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(16) All existing collections of Group 2 room air emissions at facilities that do not exceed 4 tpy of EtO use within any consecutive 12-month period after April 6, 2026, that increase their EtO use thereafter, such that the collection of Group 2 room air emissions becomes subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

(17) All new Group 2 room air emissions at facilities that increase their EtO use over a year after startup such that the Group 2 room air emissions become subject to a more stringent emission standard, immediately upon becoming subject to the more stringent emission standard.

§ 63.361 Definitions.

Terms and nomenclature used in this subpart are defined in the Clean Air Act (the Act) as amended in 1990, §§ 63.2 and 63.3, or in this section. For the purposes of this subpart, if the same term is defined in subpart A of this part and in this section, it shall have the meaning given in this section.

Acid-water scrubber means an add-on air pollution control device that uses an aqueous or alkaline scrubbing liquor to absorb and neutralize acid gases.

Aeration means, for the purposes of this rule, exposing sterilized material at elevated temperatures to drive EtO out of the material.

Aeration room means any vessel or room that is used to facilitate off-gassing of EtO at a sterilization facility. If a facility uses only combination sterilization units, for the purposes of this rule, there are no aeration rooms at the facility.

Aeration room vent (ARV) means the point(s) through which the evacuation of EtO-laden air from an aeration room occurs. For combination sterilization units, there is no ARV.

Catalytic oxidizer means a combustion device that uses a solid-phase catalyst to lower the temperature required to promote the oxidization and achieve adequate reduction of volatile organic compounds, as well as volatile hazardous air pollutants.

Chamber exhaust vent (CEV) means the point(s) through which EtO-laden air is removed from the sterilization chamber during chamber unloading following the completion of sterilization and associated air washes. This may also be referred to as a ''backvent'' (or ''back vent''). For combination sterilization units, there is no CEV.

Combination sterilization unit means any enclosed vessel in which both sterilization and aeration of the same product occur within the same vessel, *i.e.,* the vessel is filled with ethylene oxide gas or an ethylene oxide/inert gas mixture for the purpose of sterilizing and is followed by aeration of ethylene oxide.

Combined emission stream means when the emissions from more than one emission source are routed together using common ductwork prior to the control system.

Continuous monitoring system (CMS) means, for the purposes of this rule, the equipment necessary to continuously samples the regulated parameter specified in § 63.364 or § 63.365 of this subpart without interruption, evaluates the detector response at least once every 15 seconds, and computes and records the average value at least every 60 seconds, except during allowable periods of calibration and except as defined otherwise by the continuous emission monitoring system (CEMS) performance specifications (PS) in appendix B to part 60 of this chapter.

Control System Residence Time means the time elapsed from entrance of flow into the control system until gaseous materials exit the control system. For control systems with multiple exhaust streams whereby the residence time may vary for the streams, the residence time for purposes of complying with this subpart means the longest residence time for any exhaust stream in use. If a peak shaver is used, it is part of the control system, and its residence time must be considered.

Deviation means any instance in which an owner or operator of an affected source, subject to this subpart:

(1) Fails to meet any requirement or obligation established by this subpart including, but not limited to, any emission limitation, parameter value, or best management practice; or

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart or that is included in the operating permit for any facility required to obtain such a permit.

EtO dispensing means charging a sterilization chamber or chambers with EtO from non-cartridge storage media (*e.g.,* drums, cylinders) via the use of piping, lines, and other equipment. This includes injection rooms and post-injection handling of containers.

Gas/solid reactor means an add-on air pollution control device that uses a dry, solid-phase system to chemically convert EtO so that it becomes bound to the solid packing. This may also be referred to as a ''dry bed reactor'' or a ''dry bed scrubber.''

Group 1 room air emissions mean emissions from indoor EtO storage, EtO dispensing, vacuum pump operations, and pre-aeration handling of sterilized material.

Group 2 room air emissions mean emissions from post-aeration handling of sterilized material.

Indoor EtO storage means the storage of EtO within non-cartridge media (*e.g.,* drums, cylinders) inside a sterilization building.

Initial startup means the moment when an affected source subject to an emissions standard in § 63.362 first begins operation.

Injection room means any room where EtO is injected into containers (*e.g.,* bags, pouches) that are filled with product to be sterilized.

Maximum ethylene glycol concentration means the concentration of ethylene glycol in the scrubber liquor of an acid-water scrubber control device established during a performance test when the scrubber achieves the appropriate control of EtO emissions.

Maximum gas/solid reactor pressure drop means the pressure drop of the gas/solid reactor established during a performance test when the gas/solid reactor achieves the appropriate control of EtO emissions.

Maximum liquor tank level means the level of scrubber liquor in the acid-water scrubber liquor recirculation tank established during a performance test when the scrubber achieves the appropriate control of EtO emissions.

Maximum scrubber liquor pH means the pH of the acid-water scrubber liquor established during a performance test when the scrubber achieves the appropriate control of EtO emissions.

Minimum stack volumetric flow rate means the stack volumetric flow rate corrected established during a compliance demonstration when

permanent total enclosure (PTE) requirements are met.

Minimum temperature at the inlet to the catalyst bed means the temperature at the inlet to the catalyst bed established during a performance test when the catalytic oxidizer achieves the appropriate control of EtO emissions.

Minimum temperature difference across the catalyst bed means the temperature difference across the catalyst bed established during a performance test when the catalytic oxidizer achieves the appropriate control of EtO emissions.

Minimum temperature in or immediately downstream of the firebox means the temperature in or immediately downstream of the firebox established during a performance test when the thermal oxidizer achieves the appropriate control of EtO emissions.

Natural draft opening (NDO) means any permanent opening in the enclosure that remains open during operation of the facility and is not connected to a duct in which a fan is installed.

Operating day means any day that a facility is engaged in a sterilization operation.

Peak shaver means a device that is used to reduce high EtO concentrations within an exhaust stream such that the downstream control device is not overwhelmed.

Permanent total enclosure (PTE) means a permanently installed enclosure that meets the criteria of Method 204 of appendix M, 40 CFR part 51 for a PTE. A PTE completely surrounds a source of emissions such that all EtO emissions are captured, contained, and directed to a control system or to an outlet(s).

Post-aeration handling of sterilized material means the storage and transportation of material that has been removed from aeration but has not been placed in a vehicle for the sole purpose of distribution to another facility. Post-aeration handling of sterilized material ends when that vehicle is closed for the final time before leaving the facility. This definition does not include handling of material that has been both previously sterilized and not removed from aeration following re-sterilization.

Post-injection handling of containers means the storage and transportation of containers (*e.g.,* bags, pouches) that have been injected with EtO but have not been placed in a sterilization chamber.

Pre-aeration handling of sterilized material means the storage and transportation of material that has been removed from a sterilization chamber but has not been placed in an aeration room. If only combination sterilization units are used, and if material is not moved out of the vessel between sterilization and aeration, then emissions from this source do not exist. This does not include post-injection handling of containers.

Rolling sum means the weighted sum of all data, meeting QA/QC requirements or otherwise normalized, collected during the applicable rolling time period. The period of a rolling sum stipulates the frequency of data collection, summing, and reporting. As an example, to demonstrate compliance with a rolling 30-operating day sum emission reduction standard determined from hourly data, you must (1) determine the total mass of ethylene oxide prior to control and following control for each operating day; (2) then sum the current daily total mass prior to control with the previous 29 operating day total mass values and repeat the same process for the current daily total mass following control; and (3) then divide the 30-operating day total mass emissions following control by the 30-operating day total mass prior to control and subtract the resulting value from one to obtain the 30-operating day emission reduction achieved.

Single-item sterilization means a process in which one or more items are placed in a pouch, EtO is injected into the pouch, and the sealed pouch is placed in a vessel to allow sterilization to occur.

Sterilization chamber means any enclosed vessel or room that is filled with EtO gas, or an EtO/inert gas mixture, for the purpose of sterilizing and/or fumigating at a sterilization facility. This does not include injection rooms.

Sterilization chamber vent (SCV) means the point (prior to the vacuum pump) through which the evacuation of EtO from the sterilization chamber occurs following sterilization or fumigation, including any subsequent air washes.

Sterilization facility means any stationary source where EtO is used in the sterilization or fumigation of materials, including but not limited to facilities that engage in single-item sterilization.

Sterilization operation means any time when EtO is removed from the sterilization chamber through the SCV or the chamber exhaust vent, when EtO is removed from the aeration room through the aeration room vent, when EtO is stored within the building, when EtO is dispensed from a container to a chamber, when material is moved from sterilization to aeration, or when materials are handled post-aeration.

Thermal oxidizer means all combustion devices except flares.

Vacuum pump operation means the operation of vacuum pumps, excluding dry seal vacuum pumps, for the purpose of removing EtO from a sterilization chamber.

§ 63.362 Standards.

(a) *Compliance date.* If you own or operate an affected source, you must comply with the applicable requirement by the compliance date specified in § 63.360(j). The standards of this section are summarized in tables 1 through 5 to this subpart.

(b) *Applicability of standards.* The standards in paragraphs (c) through (k) of this section apply at all times. If using EtO CEMS to determine compliance with an applicable standard, this compliance demonstration is based on the previous 30-operating days of data. If using EtO CEMS to determine compliance with an applicable emission reduction standard in paragraphs (c) through (g) and (i) of this section for each operating day, you must determine the total inlet mass to and outlet mass from the control system using the procedures laid out in § 63.364(f) and appendix A to this subpart, and you must maintain the emission limit based on the inlet mass and the applicable emission reduction standard. If using EtO CEMS to determine compliance with an applicable emission reduction standard in paragraph (j) of this section, you must continuously comply with the requirements of that paragraph.

(c) *SCV.* You must comply with each applicable standard in table 1 to this subpart, and you must meet each applicable requirement specified in § 63.363. If a SCV is combined with a stream from another emission source, you must comply with the appropriate emission standard as prescribed in paragraph (i) of this section.

(d) *ARV.* You must comply with each applicable standard in table 2 to this subpart, and you must meet each applicable requirement specified in § 63.363. If an ARV is combined with a stream from another emission source, you must comply with the appropriate emission standard as prescribed in paragraph (i) of this section.

(e) *CEV.* You must comply with each applicable standard in table 3 to this subpart, and you must meet each applicable requirement specified in § 63.363. If a CEV is combined with a stream from another emission source, you must comply with the appropriate emission standard as prescribed in paragraph (i) of this section.

(f) *Group 1 room air emissions.* You must comply with the applicable

standard in table 4 to this subpart, and you must meet each applicable requirement specified in § 63.363. If Group 1 room air emissions are combined with a stream from another emission source, you must comply with the appropriate emission standard as prescribed in paragraph (i) of this section.

(g) *Group 2 room air emissions.* You must comply with the applicable standard in table 5 to this subpart, and you must meet each applicable requirement specified in § 63.363. If Group 2 room air emissions are combined with a stream from another emission source, you must comply with the appropriate emission standard as prescribed in paragraph (i) of this section. If you are required to limit the sterilization chamber concentration of EtO to 1 ppmv prior to opening the sterilization chamber door, you must meet the monitoring requirements specified in § 63.364(h).

(h) *Capture systems.* Room air emissions for which numerical limits are prescribed must be captured and routed under negative pressure to a control system. You may assume the capture system efficiency is 100 percent if both conditions in paragraphs (h)(1) and (2) of this section are met:

(1) The capture system meets the criteria in Method 204 of appendix M to 40 CFR part 51 for a PTE and directs all the exhaust gases from the enclosure to an add-on control system.

(2) All sterilization operations creating exhaust gases for which the compliance demonstration is applicable are contained within the capture system.

(i) *Requirements for combined emission streams.* When streams from two or more emission sources are combined, you must demonstrate compliance by either the approach specified in paragraph (i)(1) of this section or the approach specified in paragraph (i)(2) of this section in lieu of the applicable standards in paragraphs (c) through (g) of this section for the affected source. The combined emission stream limit is based on as 30-operating day rolling sum. In order to elect to comply with a combined emission streams limit, you must use a CEMS on each exhaust stack at the facility to determine compliance.

(1) *Monitoring after emission streams are combined.* You must follow requirements of paragraphs (i)(1)(i) through (iii) of this section to determine the applicable combined emission streams limitation and demonstrate compliance. Under this approach, you must first determine the 30-operating day rolling sum of mass inlet to the control system. Then, the emission limitation is determined by applying the most stringent emission reduction standard to the 30-operating day rolling sum of the inlet mass. You must maintain actual emissions at or below that rate. For example, suppose a facility controls all of its ARVs and CEVs with one control system and that the emission reduction standards that apply to the ARVs and CEVs are 99.9% and 99%, respectively. Further suppose that the mass of uncontrolled EtO emissions from the combined stream is 5 lb during the 30-operating day period. Under this approach, the facility would need to apply an emission reduction of 99.9% to the combined stream, resulting in an emission limit of 0.005 lb for the 30-operating day period.

(i) The combined emission streams limit for each 30-operating day period is determined daily by using equation 1 to this paragraph.

Equation 1 to paragraph (i)(2)(i)

$$CES_{Combined} = M_{30day} * (1 - Max(ER)) \quad \text{(Eq. 1)}$$

Where:

$CES_{Combined}$ = The combined emission stream limit based upon monitoring after the emission streams are combined, in pounds.

M_{30day} = The 30-operating day total mass sent to controls for the combined emission stream (*i.e.,* monitoring data at the inlet of the control system), as calculated using equation A–3 and determined in accordance with appendix A to this subpart. The term ''M_{30day}'' as used in this equation is equivalent to the term ''E_{30day}'' as designated in equation A–3.

Max(ER) = The most stringent emission reduction standard specified in tables 1 through 5 of this subpart applicable to any of the constituent streams, in decimal format.

(ii) The 30-operating day rolling sum of emissions for the combined emission stream (*i.e.,* monitoring data at the outlet of the control system) is calculated daily using equation A–3 and determined in accordance with appendix A to this subpart. For purposes of this section, this value is designated as $E_{Combined}$. If the combined emission stream is split between two or more control systems, further sum the 30-operating day rolling sum of emissions from each control system to obtain $E_{Combined}$.

(iii) Compliance with the combined emission streams limitation shall be determined by demonstrating that $E_{Combined}$, as calculated in accordance with paragraph (i)(1)(ii) of this section, for each 30-operating day period is at or below $CES_{Combined}$, as calculated in paragraph (i)(1)(i) of this section.

(2) *Monitoring before emission streams are combined.* You must follow requirements of paragraphs (i)(2)(i) through (iii) of this section to determine the applicable combined emission streams limitation and demonstrate compliance. Under this approach, you must first determine 30-operating day rolling sum of inlet mass to the control system for each component stream. Then, the emission limitation is determined by applying the applicable emission reduction standards to the 30-operating day rolling sum of each component stream and summing across the components. You must maintain actual emissions at or below that rate. For example, suppose a facility controls all of its ARVs and CEVs with one control system and that the emission reduction standards that apply to the ARVs and CEVs are 99.9% and 99%, respectively. Further suppose that during a 30-operating day period the mass of uncontrolled EtO emissions from the ARVs is 4 lb and the mass of uncontrolled EtO emissions from the CEVs is 1 lb. Under this approach, the facility would need to apply an emission reduction of 99.9% to the ARV stream and an emission reduction of 99% to the CEV stream, resulting in an emission limit of 0.014 lb for the 30-operating day period.

(i) The combined emission streams limit for each 30-operating day period is determined daily by using equation 2 to this paragraph.

Equation 2 to paragraph (i)(2)(i)

$$CES_{Streams} = \sum_{i=1}^{n} (M_{c,i} * (1 - ER_i)) + \sum_{j=1}^{m} (M_{c,j} * (1 - ER_j)) \quad \text{(Eq. 2)}$$

Where:

$CES_{Streams}$ = The combined emission stream limit based upon monitoring before the emission streams are combined, in pounds.

$M_{c,i}$ = The 30-operating day total mass sent to controls for each non-SCV constituent emission stream (*i.e.,* monitoring data at the inlet of the control system), as calculated using equation A–3 and determined in accordance with appendix A to this subpart. The term ''$M_{c,i}$'' as used in this equation is equivalent to the term ''E_{30day}'' as designated in equation A–3.

ER_i = The applicable emission reduction standard from tables 2 through 5 of this subpart to each non-SCV constituent emission stream *i.*

i = Non-SCV constituent emission stream index.

n = Total number of non-SCV constituent emission streams.

$M_{c,j}$ = The 30-operating day total mass sent to controls for each SCV emission stream, as determined in accordance with equation 10 of § 63.364(f)(1)(i)(C)(*1*).

ER_j = The applicable SCV emission reduction standard in table 1 to this subpart, in decimal format.

j = SCV emission stream index.

m = Total number of SCV emission streams.

(ii) The 30-operating day rolling sum emissions for the combined emission stream (*i.e.,* monitoring data at the outlet of the control system) is calculated daily using equation A–3 and determined in accordance with appendix A to this subpart. For purposes of this section, this value is designated as $E_{Combined}$. If the combined emission stream is split between two or more control systems, then further sum the 30-operating day rolling sum emissions from each control system to obtain $E_{Combined}$.

(iii) Compliance with the combined emission streams limitation shall be determined by demonstrating that $E_{Combined}$, as calculated in accordance with paragraph (i)(2)(ii) of this section, for each 30-operating day period is at or below $CES_{Streams}$, as calculated paragraph (i)(2)(i) of this section.

(3) If room air emissions are both subject to an emission standard and split between two or more control systems, then these control systems must be treated as part of the same control system.

(j) *Site-wide emission limitation.* You may choose to comply with a site-wide emission limitation (SWEL) specified in this paragraph (j) in lieu of the applicable standards in paragraphs (c) through (g) of this section for the facility. The SWEL, which is calculated daily, is based on the previous 30 operating days of data. In order to elect to comply with a SWEL, you must utilize an EtO CEMS on each exhaust stack at the facility to determine compliance. The owner or operator may demonstrate compliance via one of the two SWEL approaches in lieu of the applicable standard(s) in paragraphs (c) through (g) of this section for the facility. If electing to comply with a SWEL, you must comply with paragraph (j)(3) of this section.

(1) *SWEL based upon facility EtO use.* If you elect to comply with a SWEL based upon facility EtO use, you must follow requirements of paragraphs (j)(1)(i) through (iii) of this section to determine the applicable SWEL and demonstrate compliance. Under this approach, you first determine the 30-operating day rolling sum of EtO use. The SWEL is determined by multiplying by 0.99 and then applying the required SCV percent emission reduction standard in table 1 to this subpart to the 30-operating day rolling sum of EtO usage. Then, for each CEMS at the outlet of the control systems at the facility, determine the 30-operating day rolling sum of emissions. Finally, determine the facility actual emissions by summing the 30-operating day rolling sums for each CEMS at the facility. You must maintain actual emissions at or below the SWEL.

(i) The SWEL for each 30-operating day period is determined daily by using equation 3 to this paragraph.

Equation 3 to paragraph (j)(1)(i)

$$SWEL_{Fac} = M_{Fac} * 0.99 * (1 - ER_{SCV}) \quad \text{(Eq. 3)}$$

Where:

$SWEL_{Fac}$ = SWEL based upon facility EtO use, in pounds.

M_{Fac} = Facility EtO use over the previous 30 operating days, in pounds, as determined in accordance with equation 11 of § 63.364(i)(2).

0.99 = Adjustment factor for EtO residual in sterilized product.

ER_{SCV} = The applicable SCV emission reduction standard in table 1 to this subpart, in decimal format.

(ii) The 30-operating day rolling sum of emissions are determined daily using equation 4 to this paragraph.

Equation 4 to paragraph (j)(1)(ii)

$$E_{Fac} = \sum_{i=1}^{n} E_{o,i} \quad \text{(Eq. 4)}$$

Where:

E_{Fac} = The total emissions from the facility over the previous 30-operating days, in pounds.

$E_{o,i}$ = The 30-operating day rolling sum of emissions calculated at each exhaust stack, *i,* monitored by an EtO CEMS, as calculated using equation A–3 of appendix A to this subpart.

i = Exhaust stack index

n = Total number of exhaust stacks

(iii) Compliance with the SWEL based upon facility EtO usage shall be

determined by demonstrating that E_{Fac}, as calculated in accordance with paragraph (j)(1)(ii) of this section, for each 30-operating day period is at or below the SWEL, as calculated paragraph (j)(1)(i) of this section.

(2) *SWEL based upon emissions streams.* If you elect to comply with a SWEL based upon emissions streams, you must follow requirements of paragraphs (j)(2)(i) through (iii) of this section to determine the applicable SWEL and demonstrate compliance. Under this approach, for each non-SCV affected source, you must determine the mass of EtO sent to controls and apply the applicable emission reduction standard. For each SCV affected source, you must determine the mass of EtO sent to controls as specified in § 63.364(f)(1)(i)(C)(*1*) and apply the applicable emission reduction standard. The SWEL is determined by summing across the result of this calculation for each affected source (both non-SCV and SCV). Then, for each CEMS at the outlet of the control system(s) at the facility, determine the 30-operating day rolling sum of emissions. Finally, determine the facility actual emissions by summing the 30-operating day rolling sums for each CEMS at the facility. You must maintain actual emissions at or below the SWEL.

(i) The SWEL for each 30-operating day period is determined daily by using equation 5 to this paragraph.

Equation 5 to paragraph (j)(2)(i)

$$SWEL_{Streams} = \sum_{i=1}^{n} (M_{c,i} * (1 - ER_i)) + \sum_{j=1}^{m} (M_{c,j} * (1 - ER_j)) \qquad \text{(Eq. 5)}$$

Where:

$SWEL_{Streams}$ = SWEL based upon individual emissions streams, in pounds.

$M_{c,i}$ = The 30-operating day total mass sent to controls (*i.e.,* monitoring data at the inlet of the control system) for each non-SCV emission stream, as calculated using equation A–3 and determined in accordance with appendix A to this subpart. The term ''$M_{c,i}$'' as used in this equation is equivalent to the term ''E_{30day}'' as designated in equation A–3.

ER_i = The applicable emission reduction standard to each non-SCV emission stream, *i,* specified in tables 1 through 5 of this subpart, in decimal format.

i = Non-SCV emission streams index.

n = Total number of non-SCV emission streams.

$M_{c,j}$ = The 30-operating day total mass sent to controls for each SCV emission stream, as determined in accordance with equation 10 in § 63.364(f)(1)(i)(C)(*1*).

ER_j = The applicable SCV emission reduction standard in table 1 to this subpart, in decimal format.

j = SCV emission stream index.

m = Total number of SCV emission streams.

(ii) The 30-operating day rolling sum of emissions are determined daily using equation 4 to this section.

(iii) Compliance with the SWEL based upon emission streams shall be determined by demonstrating that E_{Fac}, as calculated in accordance with paragraph (j)(2)(ii) of this section, for each 30-operating day period is at or below $SWEL_{Streams}$, as calculated in paragraph (j)(2)(i) of this section.

(3) *Boundary.* The boundary for this approach includes all affected sources at the facility.

(k) *General duty.* At all times, you must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require the owner or operator to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether a source is operating in compliance with operation and maintenance requirements will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.

§ 63.363 Compliance and performance provisions.

(a) *Continuous compliance.* You must demonstrate continuous compliance with the applicable emission standard(s) using an EtO CEMS, including a shared EtO CEMS, installed and operated in accordance with the requirements of Performance Specification 19 in appendix B and Procedure 7 in appendix F to part 60 of this chapter. Alternatively, if you own or operate a facility where EtO use is less than 100 pounds/yr, you may demonstrate continuous compliance by conducting annual performance tests using the performance testing requirements in § 63.7, according to the applicability in table 6 to this subpart, the procedures listed in this section, and the test methods listed in § 63.365. If you elect to demonstrate compliance through periodic performance testing, you must also demonstrate continuous compliance with each operating limit required under this section according to the methods specified in § 63.364. If you own or operate an area source facility where EtO use is less than 100 pounds/yr where an existing collection of Group 2 room air emission is operated in accordance with the PTE requirements of EPA Method 204 of appendix M to part 51 of this chapter, you may instead conduct these performance tests once every three years.

(b) *Initial compliance for Facilities that use EtO CEMS.* To demonstrate initial compliance with an emission standard using a CEMS that measures HAP concentrations directly (*i.e.,* an EtO CEMS), the initial performance test must consist of the first 30 operating days after the certification of the CEMS according to Performance Specification 19 in Appendix B to part 40 of this chapter. The initial compliance demonstration period must be completed on or before the date that compliance must be demonstrated (*i.e.,* 180 days after the applicable compliance date). You must follow the procedures in appendix A to this subpart.

(1) The CEMS performance test must demonstrate compliance with the applicable EtO standards in tables 1 through 5 to this subpart. Alternatively, the CEMS performance test may demonstrate compliance with § 63.362(i) or (j).

(i) You may time-share your CEMS among different measurement points provided that:

(A) The measurement points are approximately equidistant from the CEMS;

(B) The sampling time at each measurement point is at least 3 times as long as the CEMS response time;

(C) The CEMS completes at least one complete cycle of operation for each shared measurement point within a 15-minute period; and

(D) The CEMS meets the other requirements of PS 19.

(2) You must collect hourly data from auxiliary monitoring systems during the performance test period, to convert the pollutant concentrations to pounds per hour.

(c) *Initial compliance demonstration where facility EtO use is less than 100 pounds per year.* If you own or operate an affected source that is both subject to an emission standard in § 63.362 and located within a facility where EtO use is less than 100 pounds per year, you may comply with paragraphs (c)(1) and (2) of this section:

(1) Conduct an initial compliance demonstration using the procedures listed in § 63.7 of this part according to the applicability in table 6 to this subpart, the procedures listed in this section, and the test methods listed in § 63.365;

(2) Complete the initial compliance demonstration within 180 days after the compliance date for the affected source as determined in § 63.360(j).

(d) *Operating limits for facility where EtO use is less than 100 lb/yr.* If annual EtO use at the facility is less than 100 lb, the procedures in paragraphs (d)(1) through (5) of this section may be used to determine compliance with the standard(s) under § 63.362(c) through (g) and to establish operating limits for each of the control devices, as applicable:

(1) You must determine the percent emission reduction of the control system used to comply with § 63.362(c) through (g) using the test methods and procedures in § 63.365(d)(1).

(2) If an acid-water scrubber(s) is used to comply with a standard, then you must establish as an operating limit:

(i) The maximum ethylene glycol concentration using the procedures described in § 63.365(e)(1)(i);

(ii) The maximum liquor tank level using the procedures described in § 63.365(e)(1)(ii); or

(iii) The maximum scrubber liquor pH using the procedures described in § 63.365(e)(1)(iii).

(3) If a thermal oxidizer(s) is used to comply with a standard, you must establish as an operating limit the minimum temperature in or immediately downstream of the firebox using the procedures described in § 63.365(e)(2).

(4) If a catalytic oxidizer(s) is used to comply with the standard, you must establish as operating limits both:

(i) The minimum temperature at the inlet to the catalyst bed using the procedures described in § 63.365(e)(3); and

(ii) The minimum temperature difference across the catalyst bed using the procedures described in § 63.365(e)(3).

(5) If a gas/solid reactor(s) is used to comply with the standard, you must establish as an operating limit the pressure drop across the media beds and conduct weekly sampling and analysis of the media. Determine the maximum gas/solid reactor pressure drop using the procedures described in § 63.365(e)(4).

(e) *Other control technology for facility where EtO use is less than 100 lb/yr.* If you are conducting a performance test using a control technology other than an acid-water scrubber, catalytic oxidizer, thermal oxidizer, or gas/solid reactor, you must provide to the Administrator information describing the design and operation of the air pollution control system, including recommendations for the parameters to be monitored that will demonstrate continuous compliance. Based on this information, the Administrator will determine the parameter(s) to be measured during the performance test. During the performance test required in paragraph (a) of this section, using the methods approved in § 63.365(e)(5), you must determine the site-specific operating limit(s) for the operating parameters approved by the Administrator. You must submit the information at least sixty days before the performance test is scheduled to begin. The information on the control technology must include the five items listed in paragraphs (1) through (5) of this section:

(1) Identification of the specific parameters you propose to use as additional operating limits;

(2) A discussion of the relationship between these parameters and emissions of regulated pollutants, identifying how emissions of regulated pollutants change with changes in these parameters and how limits on these parameters will serve to limit emissions of regulated pollutants;

(3) A discussion of how you will establish the upper and/or lower values which will establish the operating limits for these parameters;

(4) A discussion identifying the methods you will use to measure and the instruments you will use to monitor these parameters, as well as the relative accuracy and precision of these methods and instruments; and

(5) A discussion identifying the frequency and methods for recalibrating the instruments you will use for monitoring these parameters.

(f) *Other emission streams.* If the emission stream does not consist only of an SCV(s), the procedures in paragraphs (f)(1) through (3) of this section shall be used to determine initial compliance with the emission limits under § 63.362(d) through (g), as applicable:

(1) You must comply with paragraph (c) of this section, as applicable.

(2) If you are complying with a percent emission reduction standard as specified in tables 1 through 5 to this subpart, you must determine compliance with § 63.362(c) through (g), as applicable, using the test methods and procedures in § 63.365(d)(1).

(3) If you are required to operate any portion of the facility under PTE, you must initially demonstrate that the PTE meets the requirements of Method 204 of 40 CFR part 51, appendix M, and that all exhaust gases from the enclosure are delivered to a control system or stack(s). You must also meet the requirements in § 63.363(f)(3)(i) and either § 63.363(f)(3)(ii) or (iii):

(i) Maintain direction of the airflow into the enclosure at all times, verifying daily using the procedures described in § 63.364(f)(5) and meet either of the requirements.

(ii) Establish as an operating limit the *minimum volumetric flow rate through the affected stack(s)* using the procedures described in § 63.365(f)(1); or

(iii) Install, operate, calibrate, and maintain a continuous pressure differential monitoring system using the procedures described in § 63.364(f)(4).

§ 63.364 Monitoring requirements.

(a) *General requirements.* (1) If you own or operate an affected source subject to an emission standard in § 63.362, you must comply with the monitoring requirements in § 63.8, according to the applicability in table 6 to this subpart, and in this section.

(2) If you own or operate an affected source at a facility where EtO use is less than 100 lb/yr that is subject to an emission standard in § 63.362, you may monitor the parameters specified in paragraphs (b), (c), (d), (e), (g), and (i) of this section. All monitoring equipment shall be installed such that representative measurements of emissions or process parameters from the source are obtained. For monitoring equipment purchased from a vendor, verification of the operational status of the monitoring equipment shall include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system.

(3) If you own or operate an affected source that is subject to an emission standard in § 63.362 and that is required to monitor using EtO CEMS, you must

comply with paragraphs (f), (g), and (i) of this section.

(4) If you comply with the management practice for Group 2 room air emissions at area sources, you must comply with paragraph (h) of this section.

(5) You must keep the written procedures required by § 63.8(d)(2) on record for the life of the affected source or until the affected source is no longer subject to the provisions of this part, to be made available for inspection, upon request, by the Administrator. If the performance evaluation plan is revised, you must keep previous (*i.e.,* superseded) versions of the performance evaluation plan on record to be made available for inspection, upon request, by the Administrator, for a period of 5 years after each revision to the plan. The program of corrective action should be included in the plan required under § 63.8(d)(2).

(b) *Acid-water scrubbers.* If you are demonstrating continuous compliance through periodic performance testing on an acid-water scrubber(s), you must:

(1) *Ethylene glycol concentration.* Sample the scrubber liquor from the acid-water scrubber(s) and analyze and record at least once per week the ethylene glycol concentration of the scrubber liquor using the test methods and procedures in § 63.365(e)(1). Monitoring is required during a week only if the scrubber unit has been operated. You must maintain the weekly ethylene glycol concentration below the operating limit established during the most recent performance test;

(2) *Scrubber liquor tank level.* Measure and record at least once per day the level of the scrubber liquor in the recirculation tank(s). You must install, maintain, and use a liquid level indicator to measure the scrubber liquor tank level (*i.e.,* a marker on the tank wall, a dipstick, a magnetic indicator, etc.). Monitoring is required during a day only if the scrubber unit has been operated. You must maintain the daily scrubber liquor height in each recirculation tank below the applicable operating limit established during the most recent performance test; or

(3) *pH.* Monitor and record at least every 15 minutes the scrubber liquor pH. Monitoring is required when the scrubber is operating. A data acquisition system for the pH monitor shall compute and record each 3-hour average scrubber liquor pH value, rolled hourly. This must be done by first averaging the scrubber liquor pH readings obtained over a clock hour, *i.e.,* beginning and ending on the hour. All data collected during the operating hour must be used, even if the scrubber unit is not operating for a complete hour. Then, the average of the previous 3 operating hours must be calculated to determine the 3-hour rolling average scrubber liquor pH. You must maintain the 3-hour rolling average scrubber liquor pH below the applicable operating limit established during the most recent performance test. You must ensure the pH monitoring system meets the following requirements:

(i) The pH sensor must be installed in a position that provides a representative measurement of scrubber liquor pH;

(ii) The sample must be properly mixed and representative of the fluid to be measured; and

(iii) A performance evaluation (including a two-point calibration with one of the two buffer solutions having a pH within 1 of the pH of the operating limit) of the pH monitoring system must be conducted in accordance with your monitoring plan at the time of each performance test but no less frequently than quarterly.

(c) *Oxidizers.* If you are demonstrating continuous compliance through periodic performance testing on a catalytic oxidizer or thermal oxidizer, the requirements in paragraphs (c)(1) and (2) of this section apply:

(1) For thermal oxidizers, you must monitor and record at least every 15 minutes the temperature in or immediately downstream of the firebox using the temperature monitor described in paragraph (c)(4) of this section. Monitoring is required when the thermal oxidizer is operating. A data acquisition system for the temperature monitor shall compute and record each 3-hour average temperature value, rolled hourly. This must be done by first averaging the temperature readings over a clock hour, *i.e.,* beginning and ending on the hour. All data collected during the operating hour must be used, even if the thermal oxidizer is not operating for a complete hour. Then, the average of the previous 3 operating hours must be calculated to determine the 3-hour rolling average temperature in or immediately downstream of the firebox. You must maintain the 3-hour rolling average temperature above the operating limit established during the most recent performance test.

(2) For catalytic oxidizers, you must monitor and record at least every 15 minutes the temperature at the inlet to the catalyst bed using the temperature monitor described in paragraph (c)(4) of this section. Monitoring is required when the catalytic oxidizer is operating. A data acquisition system for the temperature monitor shall compute and record each 3-hour average temperature, rolled hourly. This must be done by first averaging the temperature readings over a clock hour, *i.e.,* beginning and ending on the hour. All data collected during the operating hour must be used, even if the catalytic oxidizer is not operating for a complete hour. Then, the average of the previous 3 operating hours must be calculated to determine the 3-hour rolling average temperature at the inlet to the catalyst bed. You must maintain the 3-hour rolling average temperature above the operating limit established during the most recent performance test.

(3) For catalytic oxidizers, you must monitor and record at least every 15 minutes the temperature increase across the catalyst bed, immediately downstream of the catalytic bed, using the temperature monitor described in paragraph (c)(4) of this section. Monitoring is required when the catalytic oxidizer is operating. A data acquisition system for the temperature monitor shall compute and record each 3-hour average temperature increase, rolled hourly. This must be done by first computing the difference in outlet temperature minus inlet temperature (monitored under paragraph (c)(2)), and second averaging the temperature difference values over a clock hour, *i.e.,* beginning and ending on the hour. All data collected during the operating hour must be used, even if the catalytic oxidizer is not operating for a complete hour. Then, the average of the previous 3 operating hours must be calculated to determine the 3-hour rolling average temperature increase across the catalyst bed. You must maintain the 3-hour average temperature increase above the operating limit established during the most recent performance test.

(4) You must install, calibrate, operate, and maintain a temperature monitor with a minimum accuracy of ±1 percent over the normal range of the temperature measured, expressed in degrees Celsius, or 2.8 degrees Celsius, whichever is greater. You must verify the accuracy of the temperature monitor twice each calendar year at least five months apart with a reference temperature monitor (traceable to National Institute of Standards and Technology (NIST) standards or an independent temperature measurement device dedicated for this purpose). During accuracy checking, the probe of the reference device shall be at the same location as that of the temperature monitor being tested. As an alternative, the accuracy of the temperature monitor may be verified in a calibrated oven (traceable to NIST standards).

(5) For catalytic oxidizers, if the monitor indicates that the temperature is below the operating limit, within 7 calendar days you must:

(i) Correct the temperature or temperature increase so that it falls within the established operating range; or

(ii) Replace the catalyst bed. Following replacement of the catalyst bed, you must conduct a new performance test within 180 days and re-establish the operating limits.

(d) *Gas-solid reactors.* If you are demonstrating continuous compliance through periodic performance testing on a gas/solid reactor(s), you must:

(1) *Media analysis.* Sample the media from the gas/solid reactor(s) and have the manufacturer analyze at least once per week. Monitoring is required during a week only if the gas/solid reactor unit has been operated; and

(2) *Pressure drop.* Monitor and record at least every 15 minutes the pressure drop. Monitoring is required when the gas/solid reactor is operating. A data acquisition system for the pressure drop monitor shall compute and record each 3-hour average gas/solid reactor pressure drop value, rolled hourly. This must be done by first averaging the gas/solid reactor pressure drop readings obtained over a clock hour, *i.e.,* beginning and ending on the hour. All data collected during the operating hour must be used, even if the gas/solid reactor unit is not operating for a complete hour. Then, the average of the previous 3 operating hours must be calculated to determine the 3-hour rolling average gas/solid reactor pressure drop. You must maintain the 3-hour rolling average gas/solid reactor pressure drop below the applicable operating limit established during the most recent performance test.

(e) *Performance testing, other control technology.* If you are complying with § 63.363(d) or (e) using periodic performance testing and the use of a control device other than acid-water scrubbers, catalytic or thermal oxidizers, or gas/solid reactors, you must monitor the parameters as approved by the Administrator using the methods and procedures in § 63.365(e).

(f) *EtO CEMS configurations.* If you are using EtO CEMS to demonstrate compliance with an emission standard, you must install and operate an EtO CEMS on each outlet for the control system in accordance with the requirements of Appendix A to subpart O of this part. You must also conduct monitoring for each inlet to the control system that is used to demonstrate compliance with the emission reduction standard in accordance with the requirements of appendix A to this subpart, with the exception for SCV emission streams to the control system.

(1) *EtO CEMS inlet configuration.* The following caveats apply:

(i) *SCVs.* If you do not own or operate a single-item sterilizer, to demonstrate compliance with the percent emission reduction standards for emissions streams that are comprised only of SCVs, you may use the following procedures as an alternative to monitoring the inlet emission stream to determine the mass emissions of EtO being emitted via sterilization chamber(s) vents prior to the controls.

(A) Determine the mass ($M_{SCV,n}$) of EtO used for each charge and at each sterilization chamber used during the previous 30 days using the procedures in either paragraph (f)(1)(i)(A)(*1*) or (*2*) of this section.

(*1*) Weigh the EtO gas cylinder(s) used to charge the sterilizer(s) before and after charging. Record these weights to the nearest 45 g (0.1 lb) and calculate the theoretical mass (M_c) vented to the controls using equation 1 to this paragraph.

Equation 1 to paragraph (f)(1)(i)(A)(1)

$$M_{SCV,n} = M_{charge} \times \%EO_w \quad \text{(Eq. 1)}$$

Where:

$M_{SCV,n}$ = Theoretical total mass of EtO vented to controls per charge, g (lb)

M_{charge} = total mass of sterilizer gas charge, g (lb)

$\%EO_w$ = weight percent of EtO

(*2*) Install a calibrated rate meter at the sterilizer inlet(s) and continuously measure the flow rate (Q_m) and duration of each sterilizer charge. Calculate the theoretical mass ($M_{SCV,n}$) vented to the controls using equation 2 to this paragraph.

Equation 2 to paragraph (f)(1)(i)(A)(2)

$$M_{SCV,n} = (Q_m \times T_n \times \%EO_v \times \frac{MW}{SV}) \quad \text{(Eq. 2)}$$

Where:

$M_{SCV,n}$ = theoretical total mass of EtO sent to controls per charge

Q_m = volumetric flow rate, liters per minute (L/min) corrected to 20 °C and 101.325 kilopascals (kPa) (scf per minute (scfm) corrected to 68 °F and 1 atmosphere of pressure (atm))

T_n = time duration of each charge, min

$\%EO_v$ = volume fraction percent of EtO

n = number of EtO charges

MW = molecular weight of EtO, 44.05 grams per gram-mole (g/g-mole) (44.05 pounds per pound-mole (lb/lb-mole))

SV = standard volume, 24.05 liters per gram-mole (L/g-mole) at 20 °C and 101.325 kPa (385.1 scf per pound-mole (scf/lb-mole) at 68 °F and 1 atm).

(B) Determine the adjustment factor (*f*) using equation 8 to this paragraph. Determine the mass of EtO sent to controls from all non-SCV affected sources, *I,* using equation 4 to this paragraph. For facilities where EtO use is less than 4 tpy, if not all Group 2 room air emissions are routed to a control device, do not include Group 2 room air emissions in *I,* and subtract 0.002 from this factor.

Equations 3 and 4 to paragraph (f)(1)(i)(B)

$$f = 0.99 - \frac{I}{M_{Fac}} \quad \text{(Eq. 3)}$$

Where:

f = Adjustment factor.

I = Mass of non-SCV EtO routed to control devices over the previous 30 operating days

M_{Fac} = Facility EtO use over the previous 30-operating days, in pounds, as determined in accordance with equation 11 of § 63.364(i)(2)

$$I = \sum_{i=1}^{n} M_{c,i} \quad \text{(Eq. 4)}$$

Where:

I = Mass of non-SCV EtO routed to control devices over the previous 30 operating days

$M_{c,i}$ = The 30-operating day total mass sent to controls (*i.e.,* monitoring data at the inlet of the control system) for each non-SCV emission stream, as calculated using equation A–3 and determined in accordance with appendix A to this subpart. The term ''$M_{c,i}$'' as used in this equation is equivalent to the term ''E_{30day}'' as designated in equation A–3.

i = Non-SCV emission stream index.

n = Total number of non-SCV emission streams.

(C)(*1*) Determine the mass rate of EtO sent to controls during the previous 30 days using equation 5 to this paragraph.

Equation 5 to paragraph (f)(1)(i)(C)(1)

$$M_{SCV} = f \times \sum_{i=1}^{n} M_{SCV,n} \quad \text{(Eq. 5)}$$

Where:

M_{SCV} = Total mass of EtO sent to controls over the previous 30 operating days, g/hr (lb/hr)

f = Adjustment factor

$M_{SCV,n}$ = Theoretical mass of EtO sent to controls per charge per chamber, g (lb)

n = Total number of charges during the previous 30 operating days

(*2*) If both this approach is chosen and the SCV is (or SCVs are) combined with another emission stream, then the owner or operator cannot monitor the point after the combination occurs.

(ii) *Room air emissions.* If room air emissions are both subject to an emission standard and split between two or more control systems, then monitoring must be conducted for room air emissions before they are combined with other streams.

(2) *EtO CEMS on exhaust configurations.* Exhaust gases from the emission sources under this subpart exhaust to the atmosphere through a variety of different configurations, including but not limited to individual stacks, a common stack configuration, or a main stack plus a bypass stack. For the CEMS used to provide data under this subpart, the continuous monitoring system installation requirements for these exhaust configurations are as follows:

(i) *Single unit-single stack configurations.* For an emission source that exhausts to the atmosphere through a single, dedicated stack, you shall either install the required CEMS in the stack or at a location in the ductwork downstream of all emissions control devices, where the pollutant and diluents concentrations are representative of the emissions that exit to the atmosphere.

(ii) *Unit utilizing common stack with other emission source(s).* When an emission source utilizes a common stack with one or more other emission sources, but no emission sources not subject to this rule, you shall either:

(A) Install the required CEMS in the duct from each emission source, leading to the common stack; or

(B) Install the required CEMS in the common stack.

(iii) *Unit(s) utilizing common stack with non-commercial sterilization emission source(s).* (A) When one or more emission sources shares a common stack with one or more emission sources not subject to this rule, you shall either:

(*1*) Install the required CEMS in the ducts from each emission source that is subject to this rule, leading to the common stack; or

(*2*) Install the required CEMS described in this section in the common stack and attribute all of the emissions measured at the common stack to the emission source(s).

(B) If you choose the common stack monitoring option:

(*1*) For each hour in which valid data are obtained for all parameters, you must calculate the pollutant emission rate; and

(*2*) You must assign the calculated pollutant emission rate to each of the units subject to the rule that share the common stack.

(iv) *Unit with multiple parallel control devices with multiple stacks.* If the exhaust gases from an emission source, which is configured such that emissions are controlled with multiple parallel control devices or multiple series of control devices are discharged to the atmosphere through more than one stack, you shall install the required CEMS described in each of the multiple stacks. You shall calculate hourly, flow-weighted, average pollutant emission rates for the unit as follows:

(A) Calculate the pollutant emission rate at each stack or duct for each hour in which valid data are obtained for all parameters;

(B) Multiply each calculated hourly pollutant emission rate at each stack or duct by the corresponding hourly gas flow rate at that stack or duct;

(C) Sum the products determined under paragraph (f)(2)(iv)(B) of this section; and

(D) Divide the result obtained in paragraph (f)(2)(I(C) of this section by the total hourly gas flow rate for the unit, summed across all of the stacks or ducts.

(g) *PTE monitoring.* If you are required to operate all or a portion of your sterilization facility under PTE conditions, you must:

(1) *Initial compliance.* Demonstrate initial procedures in § 63.365(g)(1) and continued compliance with the provisions in this section. You must follow the requirements of either paragraphs (g)(2) and (3) of this section or paragraph (g)(4) of this section.

(2) *Continuous compliance.* If you choose to demonstrate continuous compliance through volumetric flow rate monitoring, you must monitor and record at least every 15 minutes the volumetric flow rate from each outlet where air from the PTE is sent using a flow rate monitoring system described in paragraph (g)(3) of this section. Monitoring is required when the portion of the facility covered by PTE is operated. A data acquisition system for the flow rate monitoring system shall compute and record each 3-hour average flow rate value, rolled hourly. This must be done by first averaging the flow rate readings over a clock hour, *i.e.,* beginning and ending on the hour. All data collected during the operating hour must be used, even the portion of the facility covered by PTE is not operated for a complete hour. Then, the average of the previous 3 operating hours must be calculated to determine the 3-hour rolling average flow rate. You must maintain the 3-hour rolling average flow rate above the applicable operating limits established during the most recent compliance demonstration.

(3) *Continuous flow rate monitoring system for PTE.* You must install, operate, calibrate, and maintain instruments, according to the requirements in paragraphs (g)(3)(i) through (ix) of this section, for continuously measuring and recording the stack gas flow rate to allow determination of compliance with the minimum volumetric flow rate through the affected stack operating limit(s).

(i) You must install each sensor of the flow rate monitoring system in a location that provides representative measurement of the exhaust gas flow rate. The flow rate sensor is that portion of the system that senses the volumetric flow rate and generates an output proportional to that flow rate.

(ii) The flow rate monitoring system must be designed to measure the exhaust flow rate over a range that extends from a value of at least 20 percent less than the lowest expected exhaust flow rate to a value of at least 20 percent greater than the highest expected exhaust flow rate.

(iii) The flow rate monitoring system must be equipped with a data acquisition and recording system that is capable of recording values over the entire range specified in paragraph (g)(3)(ii) of this section.

(iv) The signal conditioner, wiring, power supply, and data acquisition and recording system for the flow rate monitoring system must be compatible with the output signal of the flow rate sensors used in the monitoring system.

(v) The flow rate monitoring system must be designed to complete a minimum of one cycle of operation for each successive 15-minute period.

(vi) The flow rate sensor must have provisions to determine the daily zero and upscale calibration drift (CD) (*see* sections 3.1 and 8.3 of Performance Specification 2 in appendix B to Part 60 of this chapter for a discussion of CD).

(A) Conduct the CD tests at two reference signal levels, zero (*e.g.,* 0 to 20 percent of span) and upscale (*e.g.,* 50 to 70 percent of span).

(B) The absolute value of the difference between the flow monitor response and the reference signal must be equal to or less than 3 percent of the flow monitor span.

(vii) You must perform an initial relative accuracy test of the flow rate monitoring system according to section 8.2 of Performance Specification 6 of appendix B to part 60 of the chapter with the exceptions in paragraphs (g)(3)(vii)(A) and (B) of this section.

(A) The relative accuracy test is to evaluate the flow rate monitoring system alone rather than a continuous emission rate monitoring system.

(B) The relative accuracy of the flow rate monitoring system shall be no greater than 10 percent of the mean value of the reference method data.

(viii) You must verify the accuracy of the flow rate monitoring system at least once per year by repeating the relative accuracy test specified in paragraph (g)(3)(vii) of this section.

(ix) You must operate the flow rate monitoring system and record data during all periods of operation of the affected facility including periods of startup, shutdown, and malfunction.

(4) *Pressure differential monitor.* You must instead install, operate, calibrate, and maintain a continuous pressure differential monitoring system, as follows, to verify the presence of PTE. You must operate this system whenever the facility is in operation. You must also maintain the pressure differential at or above 0.007 inches of water over a three-hour rolling average.

(i) This monitoring system must measure the pressure differential between the interior and exterior of the PTE, with at least one monitoring device located in each room that borders the PTE. These monitoring devices shall be designed to provide measurements of pressure differential to at least the nearest 0.001 inches of water and having a complete cycle time no greater than 5 minutes.

(ii) A data acquisition system for the monitoring system shall compute and record each 3-hour average pressure differential value, rolled hourly. This must be done by first averaging the pressure differential readings over a clock hour, *i.e.,* beginning and ending on the hour. All data collected during the operating hour must be used, even in portions of the facility covered by PTE that are not operated for a complete hour. Then, the average of the previous 3 operating hours must be calculated to determine the 3-hour rolling average pressure differential. If data are not recorded from an alternative monitoring device, during any malfunction of the principal monitoring device(s) or the automatic recorder, you must manually record the measured data at least hourly.

(h) *Sterilization chamber end-cycle EtO concentration.* As part of your monitoring plan, you must document your approach for determining the EtO sterilization chamber concentration. If you choose a parametric approach you must meet the requirements in paragraph (h)(1) of this section and if you choose a direct measurement approach you must meet the requirements in paragraph (h)(2) of this section. Alternatively, you may petition the administrator for an alternative monitoring approach under § 63.8(f).

(1) If you choose a parametric approach for determining chamber EtO concentrations you must document parameter(s) used in the calculation to determine of EtO concentrations and the calculation(s) used to determine the chamber concentration. Any instrumentation used for parametric monitoring must also be identified in the monitoring plan and at a minimum this plan should include the following for each instrument:

(i) Parameter measured and measurement principle of the monitor.

(ii) Instrument name, model number, serial number, and range.

(iii) Manufacturer recommended operation practices, including daily operational check.

(iv) Procedures for calibration, the frequency of calibration, and accuracy requirements of the calibration.

(v) Description for how the information from the parameter monitor is being collected and stored.

(2) If you choose a direct measurement approach for determining chamber EtO calibrations you must document the procedures used for the operation of the instruments. Any instrument used for direct measurement of EtO must be identified in the monitoring plan and at a minimum this plan must include the following information:

(i) Instrument name, model number, serial number, and range.

(ii) Description of the measurement principle and any potential interferences.

(iii) If applicable, the description of the sampling condition system.

(iv) Procedures for calibration, the frequency of calibration, and accuracy requirements of the calibration.

(v) Description for how the information from the parameter monitor is being collected and stored.

(i) *EtO usage.* If you own or operate a sterilization facility subject to the requirements of this subpart you must monitor and record on a daily basis the daily and 30-operating day EtO usage according to the requirements of this paragraph. Additionally, you must record EtO usage for each calendar month.

(1) Monitor and record on a daily basis, the daily total mass of ethylene oxide, in pounds, used at the facility. The daily total mass must be determined using the methodology specified in § 63.365(c)(1)(i) and (ii).

(2) Determine and record daily the 30-operating day rolling ethylene oxide usage rate using equation 6 to this paragraph.

Equation 6 to paragraph (i)(2)

$$M_{Fac} = \sum_{i=1}^{30} m_{Fac,i} \qquad \text{(Eq. 6)}$$

Where:

M_{Fac} = Facility EtO use over the previous 30 operating days, in pounds.

$m_{Fac,i}$ = Daily EtO use for operating day *i,* in pounds, as determined in accordance with paragraph (i)(1) of this section

i = Operating day index.

(3) Determine and record the total mass of EtO used in each calendar month.

§ 63.365 Test methods and procedures.

(a) *General*—(1) *Performance testing for facility where EtO use is less than 100 pounds per year.* If you own or operate an affected source at a facility where EtO use is less than 100 lb/yr that is subject to an emission standard in § 63.362, you must comply with the performance testing requirements in § 63.7, according to the applicability in table 6 to this subpart, using the methods in paragraph (b) or (c) of this section, following the applicable procedures for initial compliance and continuous compliance in paragraphs (d), (e), and (f) of this section.

(2) *Facilities subject to capture efficiency.* If you are subject to capture efficiency requirements in § 63.362, you must follow the applicable procedures for initial and continuous compliance in paragraph (f) of this section.

(b) *Test methods for facility where EtO use is less than 100 pounds per year.* You must use the following test methods to determine the average mass emissions of EtO in lb/hr at the inlet of a control system ($M_{APCD,\ i}$) and/or outlet of a control system or stack ($E_{APCD,\ o}$).

(1) Select the location of the sampling ports and the number of traverse points according to Method 1 of appendix A–1 to part 60 of this chapter. Alternatively, for ducts less than 0.3 meter (12 in.) in diameter, you may choose to locate sample ports according to Method 1A of appendix A–1 to part 60 of this chapter.

(2) Determine the flow rate through the control system exhaust(s) continuously during the test period according to either Methods 2, 2A, or 2C of appendix A–1 to part 60 of this chapter, as appropriate. If using Method 2, 2A, or 2C, you must complete velocity traverses immediately before and subsequently after each test run. If your test run is greater than 1 hour, you must also complete a velocity traverse at least every hour. Average the velocity collected during a test run and calculate volumetric flow as outlined in the appropriate method.

(3) Determine the oxygen and carbon dioxide concentration of the effluent according to Method 3A or 3B of appendix A–2 to part 60 of this chapter. The manual procedures (but not instrumental procedures) of voluntary consensus standard ANSI/ASME PTC 19.10–1981 (incorporated by reference, see § 63.14) may be used as an alternative to EPA Method 3B.

(4) Determine the moisture content of the stack gas according to Method 4 of appendix A–3 to part 60 of this chapter. Alternatively, you may use an on-line technique that has been validated using Method 301 of appendix A to this part.

(5) Determine the EtO concentration according to either paragraph (b)(5)(i) or (ii) of this section.

(i) Follow Method 320 of appendix A to this part and the following paragraphs (5)(i)(A) through (D).

(A) The instrumentation used for measurement must have the measurement range to properly quantify the EtO in the gas stream. Additionally, for outlet emission streams, the instrumentation must have a method detection limit an order of magnitude below concentration equivalent of the emission limit.

(B) Instrumentation used must be continuous in nature with an averaging time of one minute or less.

(C) Calibration Spectra and all other analyte spiking required in the method must use EtO gaseous cylinder standard(s) which meet the criteria found in Performance Specification 19 of appendix B to part 60 if this chapter.

(D) Other methods and materials may be used; however, these alternative test methods are subject to Administrator approval.

(ii) Alternatively, ASTM D6348–12 (Reapproved 2020), (incorporated by reference, see § 63.14) may be used with the following conditions:

(A) The test plan preparation and implementation in the Annexes to ASTM D 6348–12 (R2020), Sections A1 through A8 are mandatory; and

(B) In ASTM D6348–12 (R2020) Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (equation A5.5). In order for the test data to be acceptable

for a compound, %R must be 70% ≥ R ≤ 130%. If the %R value does not meet this criterion for a target compound, the test data is not acceptable for that compound and the test must be repeated for that analyte (*i.e.,* the sampling and/or analytical procedure should be adjusted before a retest). The %R value for each compound must be reported in the test report, and all field measurements must be corrected with the calculated %R value for that compound by using equation 1 to this paragraph:

Equation 1 to paragraph (b)(5)(ii)

Reported Results = ((Measured Concentration in Stack))/(%R) x 100.]

(6) Calculate the mass emission of EtO by using equations 2 and 3 to this paragraph:

Equations 2 and 3 to paragraph (b)(6)

$$M_{APCD,in} = \frac{C_{Eto,i} \text{ x } Q_i \text{ x } 44.05}{385.1 \text{ x } 10^6} \quad \text{(Eq. 2)}$$

$$E_{APCD,o} = \frac{C_{EtO,o} \text{ x } Q_o \text{ x } 44.05}{385.1 \text{ x } 10^9} \quad \text{(Eq. 3)}$$

Where:

$M_{APCD, i}$ = average inlet mass rate of EtO per hour, lb/hr

$C_{EtO,i}$ = inlet EtO concentration, ppmdv.

Qi = average inlet volumetric flow per hour at standard conditions, dscf/hr

44.05 = molecular weight (MW) of EtO, lb/lb-mole

MW/385.1 × 10^6 = conversion factor, from ppmv at standard conditions to lb/cf

$E_{APCD, o}$ = average outlet mass rate of EtO per hour, lb/hr

$C_{EtO,o}$ = outlet EtO concentration, ppbdv.

Q_o = average outlet volumetric flow per hour at standard conditions, dscf/hr

MW/385.1 × 10^9 = conversion factor, from ppbv at standard conditions to lb/cf

(c) *Alternative approach for SCVs for facility where EtO use is less than 100 pounds per year.* If you do not own or operate a single-item sterilizer, to demonstrate compliance with the percent emission reduction standards for emissions streams that are comprised only of SCVs, you may use the following procedures as an alternative to paragraph (b) of this section to determine the mass emissions of EtO being emitted via sterilization chamber(s) vents prior to the controls.

(1) Determine the mass ($M_{SCV,n}$) of EtO used for each charge and at each sterilization chamber used during the performance tests using the procedures in either paragraph (c)(1)(i) or (ii) of this section.

(i) Weigh the EtO gas cylinder(s) used to charge the sterilizer(s) before and after charging. Record these weights to the nearest 45 g (0.1 lb) and calculate the theoretical mass ($M_{SCV,n}$) vented to the controls using equation 4 to this paragraph.

Equation 4 to paragraph (c)(1)(i)

$$M_{SCV,n} = M_{charge} \text{x } \%EO_w \quad \text{(Eq. 4)}$$

Where:

$M_{SCV,n}$ = Theoretical total mass of EtO vented to controls per charge, g (lb)

M_{charge} = total mass of sterilizer gas charge, g (lb)

%E.O.$_w$ = weight percent of EtO

(ii) Install a calibrated rate meter at the sterilizer inlet(s) and continuously measure the flow rate (Q_m) and duration of each sterilizer charge. Calculate the theoretical mass ($M_{SCV,n}$) vented to the controls using equation 5 to this paragraph.

Equation 5 to paragraph (c)(1)(ii)

$$M_{SCV,n} = \left(Q_m \text{ x } T_n \text{ x } \%EO_v \text{ x } \frac{MW}{SV}\right) \quad \text{(Eq. 5)}$$

Where:

$M_{SCV,n}$ = Total mass of EtO sent to controls per charge

Q_m = volumetric flow rate, liters per minute (L/min) corrected to 20 °C and

101.325 kilopascals (kPa) (scf per minute (scfm) corrected to 68 °F and 1 atmosphere of pressure (atm))
T_n = time duration of each charge, min
$_n$ = number of EtO charges
$\%E.O._v$ = volume fraction percent of EtO
MW = molecular weight of EtO, 44.05 grams per gram-mole (g/g-mole) (44.05 pounds per pound-mole (lb/lb-mole))
SV = standard volume, 24.05 liters per gram-mole (L/g-mole) at 20 °C and 101.325 kPa (385.1 scf per pound-mole (scf/lb-mole) at 68 °F and 1 atm).

(2) Determine the mass rate of EtO sent to controls during the performance test using equation 6 to this paragraph.

Equation 6 to paragraph (c)(2)

$$M_{SCV} = \frac{\sum_{i=1}^{n} M_{SCV,n}}{T_t} \times f \qquad \text{(Eq. 6)}$$

Where:

M_{SCV} = Total mass of EtO sent to controls per hour, g/hr (lb/hr)
$M_{SCV,n}$ = Total mass of EtO sent to controls per charge per chamber, g (lb)
T_t = Total time of the performance test, hour
n = Total number of charges during testing period
f = Portion of EtO use that is assumed to be routed to the control system (0.93 if aeration is conducted in separate vessel; 0.98 otherwise)

(d) *Compliance determination for facility where EtO use is less than 100 pounds per year.* Each compliance demonstration shall consist of three separate runs using the applicable methods in paragraph (b) or (c) of this section. To determine compliance with the relevant standard, arithmetic mean of the three runs must be used. These procedures may be performed over a run duration of 1-hour (for a total of three 1-hour runs), except for the SCV testing from this category, where each run shall consist of the entirety of the sterilizer chamber evacuation and subsequent washes. The owner or operator may not conduct performance tests during periods of malfunction. The owner or operator must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent the entire range of normal operation, including operational conditions for maximum emissions if such emissions are not expected during maximum production. The owner or operator must also account for the control system residence time when conducting the performance test. Upon request, the owner or operator shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests. The following procedures shall be used to demonstrate compliance with a removal efficiency standard. In addition to these procedures, the procedures in paragraph (e) of this section must be followed to establish the operating parameter limits for each applicable emission control(s).

(1) You may determine the mass rate emissions of the stream prior to the control system and at the outlet of the control system using the test methods in paragraph (b) of this section. If the vent stream is comprised only of one or more SCVs, then you may use the procedures in paragraph (c) of this section for the mass rate emissions at the inlet.

(2) Calculate the total mass of EtO per hour that is routed to the control system by summing the mass of EtO per hour from each vent.

(3) Determine percent emission reduction (%ER) using the equation 7 to this paragraph:

Equation 7 to paragraph (d)(3)

$$\%ER = \frac{M_{APCD,i} - E_{APCD,o}}{M_{APCD,i}} \times 100 \qquad \text{(Eq. 7)}$$

Where:

% ER = percent emission reduction
$M_{APCD,i}$ = total mass of EtO per hour to the control device
$E_{APCD,o}$ = total mass of EtO per hour from the control device

(4) Repeat these procedures two additional times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control system.

(e) *Determination of operating limits for control device(s).* If you are using performance testing to demonstrate compliance with removal efficiency standards, and if you are not demonstrating continual compliance with the applicable standard(s) using an EtO CEMS, you must also determine the operating limit(s) for each control device and then monitor the parameter(s) for each control device. The procedures in the following paragraphs shall be used to establish the parameter operating limits to be continually monitored in § 63.364.

(1) *Acid-water scrubbers.* The procedures in paragraph (e)(1) of this section shall be used to determine the operating limits for acid-water scrubbers.

(i) *Ethylene glycol concentration.* For determining the ethylene glycol concentration operating limit, you must establish the maximum ethylene glycol concentration as the ethylene glycol concentration averaged over three test runs; use the sampling and analysis procedures in ASTM D3695–88 (incorporated by reference, see § 63.14) to determine the ethylene glycol concentration.

(ii) *Scrubber liquor tank level.* During the performance test, you must monitor and record the scrubber liquor tank level to the nearest ¼ inch at the end of each of the three test runs. Use the data collected during the most recent performance test to calculate the average scrubber liquor tank level. This scrubber liquor tank level is the maximum operating limit for your scrubber liquor tank. Repeat this procedure for every scrubber liquor tank that is included in the performance test.

(iii) *Scrubber liquor pH.* During the performance test, you must monitor and record the scrubber liquor pH at least once every 15 minutes during each of the three test runs. You must use pH

monitors as described in § 63.364(b)(3). Use the data collected during the most recent performance test to calculate the average scrubber pH measured. This scrubber liquor pH is the maximum operating limit for your acid-water scrubber. Repeat this procedure for every scrubber liquor tank that is included in the performance test.

(2) *Thermal oxidizers.* The procedures in this paragraph shall be used to determine the operating limits for thermal oxidizers.

(i) During the performance test, you must monitor and record the temperature at least once every 15 minutes during each of the three test runs. You must monitor the temperature in the firebox of the thermal oxidizer or immediately downstream of the firebox. You must use temperature monitors as described in § 63.364(c)(4).

(ii) Use the data collected during the performance test to calculate and record the average temperature for each test run maintained during the performance test. The average temperature of the test runs is the minimum operating limit for your thermal oxidizer, unless it exceeds the recommended maximum oxidation temperature provided by the oxidation unit manufacturer. If this occurs, the minimum operating limit for your thermal oxidizer consists of the recommended maximum oxidation temperature provided by the oxidation unit manufacturer.

(iii) Paragraphs (e)(2)(i) and (ii) of this section must be completed for each thermal oxidizer that is involved in the performance test.

(3) *Catalytic oxidizers.* The procedures in this paragraph shall be used to determine the operating limits for catalytic oxidizers.

(i) Prior to the start of the performance test, you must check the catalyst bed for channeling, abrasion, and settling. If problems are found during the inspection, you must replace the catalyst bed or take other correction action consistent with the manufacturer's recommendations.

(ii) During the performance test, you must monitor and record the temperature at the inlet to the catalyst bed and the temperature difference across the catalyst bed at least once every 15 minutes during each of the three test runs. You must use temperature monitors as described in § 63.364(c)(4).

(iii) Use the data collected during the performance test to calculate and record the average temperature at the inlet to the catalyst bed and the average temperature difference across the catalyst bed maintained for each test run, and then calculate the arithmetic averages of the test runs. These arithmetic averages of the test runs are the minimum operating limits for your catalytic oxidizer, unless it exceeds the recommended maximum oxidation temperature provided by the oxidation unit manufacturer. If this occurs, the minimum operating limit for your catalytic oxidizer consists of the recommended maximum oxidation temperature provided by the oxidation unit manufacturer.

(iv) Paragraphs (e)(3)(i) through (iii) of this section must be completed for each catalytic oxidizer that is involved in the performance test.

(4) *Gas/solid reactors.* During the performance test, you must monitor and record the gas/solid reactor pressure drop at least once every 15 minutes during each of the three test runs. Use the data collected during the most recent performance test to calculate the gas/solid reactor pressure measured. This gas/solid reactor pressure is the maximum operating limit for your gas/solid. Repeat this procedure for every gas/solid reactor that is included in the performance test.

(5) *Other control system for facility where EtO use is less than 100 pounds per year.* If you seek to demonstrate compliance with a standard found at § 63.362 with a control device other than an acid-water scrubber, catalytic oxidizer, thermal oxidizer, or gas/solid reactor, you must provide to the Administrator the information requested under § 63.363(e). You must submit a monitoring plan that contains the following items: a description of the device; test results collected in accordance with § 63.363(e) verifying the performance of the device for controlling EtO emissions to the atmosphere to the levels required by the applicable standards; the appropriate operating parameters that will be monitored, identifying the ongoing QA procedures and performance specifications that will be conducted on the instruments; the frequency of conducting QA and performance checks; and the frequency of measuring and recording to establish continuous compliance with the standards. Your monitoring plan is subject to the Administrator's approval. Upon approval by the Administrator you must install, calibrate, operate, and maintain the monitor(s) approved by the Administrator based on the information submitted in your monitoring plan. You must include in your monitoring plan proposed performance specifications and quality assurance procedures for your monitors. The Administrator may request further information and shall approve appropriate test methods and procedures.

(f) *Determination of compliance with PTE requirement.* If you are required to operate any portion of your facility with PTE, you must demonstrate initial compliance with the requirements of this subpart by following the procedures of paragraphs (f)(1) through (3) of this section, as applicable, during the initial compliance demonstration or during the initial certification of the CEMS tests.

(1) Determine the capture efficiency by verifying the capture system meets the criteria in section 6 of Method 204 of appendix M to part 51 of this chapter and directs all the exhaust gases from the enclosure to an add-on control device.

(2) Ensure that the air passing through all NDOs flows into the enclosure continuously. If the facial velocities (FVs) are less than or equal to 9,000 meters per hour (492 feet per minute), the continuous inward flow of air shall be verified by continuous observation using smoke tubes, streamers, tracer gases, or other means approved by the Administrator over the period that the volumetric flow rate tests required to determine FVs are carried out. If the FVs are greater than 9,000 meters per hour (492 feet per minute), the direction of airflow through the NDOs shall be presumed to be inward at all times without verification.

(3) If you are demonstrating continuous compliance through monitoring the volumetric flow rate, you must monitor and record the volumetric flow rate (in cubic feet per second) from the PTE through the stack(s) at least once every 15 minutes during each of the three test runs. Use the data collected during the most recent compliance demonstration to calculate the average volumetric flow rate measured during the compliance demonstration. This volumetric flow rate is the minimum operating limit for the stack. Repeat this procedure for every stack that is included in the compliance demonstration.

§ 63.366 Reporting requirements.

(a) *General requirements.* The owner or operator of an affected source subject to the emissions standards in § 63.362 must fulfill all reporting requirements in § 63.10(a), (d), (e), and (f), according to the applicability in table 6 to this subpart. These reports will be made to the Administrator at the appropriate address identified in § 63.13 or submitted electronically.

(b) *Initial compliance report submission.* You must submit an initial compliance report that provides summary, monitoring system

performance, and deviation information to the Administrator on April 5, 2027, or once the report template for this subpart has been available on the Compliance and Emissions Data Reporting Interface (CEDRI) website for one year, whichever date is later, to the EPA via CEDRI, which can be accessed through the EPA's Central Data Exchange (CDX) (*https://cdx.epa.gov/*). The EPA will make all the information submitted through CEDRI available to the public without further notice to you. Do not use CEDRI to submit information you claim as confidential business information (CBI). Anything submitted using CEDRI cannot later be claimed CBI. You must use the appropriate electronic report template on the CEDRI website (*https://www.epa.gov/electronic-reporting-air-emissions/cedri*) for this subpart. The date report templates become available will be listed on the CEDRI website. The report must be submitted by the deadline specified in this subpart, regardless of the method in which the report is submitted. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim, submit a complete report, including information claimed to be CBI, to the EPA. The CBI report must be generated using the appropriate form on the CEDRI website or an alternate electronic file consistent with the extensible markup language (XML) schema listed on the CEDRI website. Submit the CBI file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Commercial Sterilization Facilities Sector Lead, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph. All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available. Reports of deviations from an operating limit shall include all information required in § 63.10(c)(5) through (13), as applicable in table 6 to this subpart, along with information from any calibration tests in which the monitoring equipment is not in compliance with Performance Specification 19 in appendix B and Procedure 7 in appendix F to part 60 of this chapter or the method used for parameter monitoring device calibration. Reports shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report. If your report is submitted via CEDRI, the certifier's electronic signature during the submission process replaces this requirement. When no deviations have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report. In addition, the summary report shall include:

(1) The following information:

(i) Date that facility commenced construction or reconstruction;

(ii) Hours of commercial sterilization operation over the previous 12 months; and

(iii) Monthly EtO use, in tons, over the previous 36 months.

(iv) If you are electing to determine the mass of EtO sent to the control device from the SCV(s) via the procedure in § 63.364(f)(1)(i), you must report the daily EtO use from each applicable chamber for the previous 7 months.

(v) An indication if you are required to comply with one or more combined emission stream limitations. If so, indicate the affected sources that are included in each combined emission stream limitation.

(vi) An indication if you are electing to comply with a site-wide emission limit. If you are electing to comply with a site-wide emission limit, report the daily EtO use over the previous 7 months.

(2) If your sterilization facility is demonstrating continuous compliance through periodic performance testing, you must report the following:

(i) Control system ID;

(ii) Control device ID;

(iii) Control device type; and

(iv) Recirculation tank ID if an acid-water scrubber is used to meet the emission standard and you elect to comply with the maximum scrubber liquor height limit;

(3) You must report the following for each sterilization chamber at your facility:

(i) The sterilization chamber ID;

(ii) The ID of the control system that the SCV was routed to, if applicable;

(iii) The portion of SCV exhaust that was routed to the control system, if applicable;

(iv) The ID of the EtO CEMS that was used to monitor SCV emissions, if applicable;

(v) The portion of SCV exhaust that was monitored with the EtO CEMS, if applicable;

(vi) The ID of the control system that the CEV was routed to, if applicable;

(vii) The portion of CEV exhaust that was routed to the control system, if applicable;

(viii) The ID of the EtO CEMS that was used to monitor CEV emissions, if applicable;

(ix) The portion of CEV exhaust that was monitored with the EtO CEMS, if applicable;

(4) If emissions from any room in your facility are subject to an emission standard, you must report the following for each room where there is the potential for EtO emissions:

(i) Room ID;

(ii) Documentation of emissions occurring within the room, including aeration, EtO storage, EtO dispensing, pre-aeration handling of sterilized material, and post-aeration handling of sterilized material;

(iii) The ID of the control system that the room air was routed to, if applicable;

(iv) The portion of room air that was routed to the control system, if applicable;

(v) The ID of the EtO CEMS that was used to monitor room air emissions, if applicable;

(vi) The portion of room air that was monitored with the EtO CEMS, if applicable;

(5) If an EtO CEMS was used to demonstrate continuous compliance with an emission standard for more than 30-operating days, you must report the following:

(i) The information specified in section 11 of appendix A to this subpart.

(ii) The affected sources that are included in each inlet that is being monitored with EtO CEMS;

(iii) The IDs of each inlet(s) to and outlet(s) from each control system.

(iv) The daily sum of EtO for each inlet, along with 30-operating day rolling sums.

(v) The daily sum of EtO emissions from each outlet of the control system, along with 30-operating day rolling sums.

(vi) For each day, calculate and report the daily mass emission limit that the control system must achieve based on the previous 30 days of data. For control systems with multiple emission streams, and complying with a combined emission stream limitation in § 63.362(i) or a SWEL in § 63.362(j), report the daily 30-operating day mass emission limit as determined in accordance with CES in § 63.362(i)(1)(i) and (i)(2)(i) or with § 63.362(j)(1)(i) and (j)(2)(i), as applicable.

(vii) For each day, the mass of EtO emitted from the control system over the previous 30 operating days.

(6) If any portion of your facility is required to be operated with PTE, you must report the following:

(i) If you are choosing to demonstrate continuous compliance through the use of volumetric flow rate monitoring, you must report the 3-hr rolling average, rolled hourly volumetric flow from each outlet where air from the PTE is sent, in cubic feet per second.

(ii) If you are choosing to demonstrate continuous compliance through use of differential pressure monitoring, you must report the 3-hr rolling average, rolled hourly pressure differential reading, in inches water.

(7) If you are complying with the requirement to follow the best management practice to limit sterilization chamber concentration of EtO to 1 ppmv prior to opening the sterilization chamber door, you must provide a certification from your responsible official that this approach is being followed and you are meeting the monitoring requirements at § 63.362(h).

(8) If you own or operate an existing collection of Group 2 room air emissions at an area source facility and facility EtO use is less than 4 tpy, you must report the following for each room where there are Group 2 room air emissions:

(i) Room ID;

(ii) Number of room air changes per hour;

(iii) Room temperature, in degrees Celsius; and

(iv) EtO concentration, in ppmv dry basis (ppbvd).

(9) If you own or operate an existing collection of Group 2 room air emissions at an area source facility and EtO use is less than 4 tpy, you are not required to report the information in paragraph (b)(8) of this section if you meet the following requirements:

(i) You are complying with the best management practice to limit sterilization chamber concentration of EtO to 1 ppmv prior to opening the sterilization chamber door; and

(ii) The requirements of § 63.363 are met.

(10) Report the number of deviations to meet an applicable standard. For each instance, report the date, time, the cause and duration of each deviation. For each deviation the report must include a list of the affected sources or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to determine the emissions.

(c) *Quarterly compliance report submission.* You must submit compliance reports that provide summary, monitoring system performance, and deviation information to the Administrator within 30 days following the end of each calendar quarter. Beginning on April 5, 2027, or once the report template for this subpart has been available on the Compliance and Emissions Data Reporting Interface (CEDRI) website for 1 year, whichever date is later, submit all subsequent reports to the EPA via CEDRI, which can be accessed through the EPA's CDX (*https://cdx.epa.gov/*). The EPA will make all the information submitted through CEDRI available to the public without further notice to you. Do not use CEDRI to submit information you claim as CBI. Anything submitted using CEDRI cannot later be claimed CBI. You must use the appropriate electronic report template on the CEDRI website (*https://www.epa.gov/electronic-reporting-air-emissions/cedri*) for this subpart. The date report templates become available will be listed on the CEDRI website. The report must be submitted by the deadline specified in this subpart, regardless of the method in which the report is submitted. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim, submit a complete report, including information claimed to be CBI, to the EPA. The CBI report must be generated using the appropriate form on the CEDRI website or an alternate electronic file consistent with the XML schema listed on the CEDRI website. Submit the CBI file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Commercial Sterilization Facilities Sector Lead, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph. All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Reports of deviations from an operating limit shall include all information required in § 63.10(c)(5) through (13), as applicable in table 6 to this subpart, and information from any calibration tests in which the monitoring equipment is not in compliance with Performance Specification 19 in appendix B and Procedure 7 in appendix F to part 60 of this chapter or the method used for parameter monitoring device calibration. Reports shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report. If your report is submitted via CEDRI, the certifier's electronic signature during the submission process replaces this requirement. When no deviations have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report. In addition, the summary report shall include:

(1) The information listed in paragraphs (b)(1)(i) through (vi) of this section, with the exception that monthly EtO use, in tons, only needs reported for the previous 12 months;

(2) If your sterilization facility is demonstrating continuous compliance through periodic performance testing, you must report the ID for any control system that has not operated since the end of the period covered by the previous compliance report. If a control system has commenced operation since end of the period covered by the previous compliance report, or if any of the information in paragraphs (b)(2)(i) through (iv) of this section has changed for a control system that was included in the previous compliance report, you must report the information in paragraphs (b)(2)(i) through (iv) of this section for those control systems;

(3) You must report the ID for any sterilization chamber that has not operated since then end of the period covered by the previous compliance report. If a sterilization chamber has commenced operation since the end of the period covered by the previous compliance report, or if any of the information in paragraphs (b)(3)(i) through (ix) of this section has changed for a sterilization chamber that was included in the previous compliance report, you must report the information in paragraphs (b)(3)(i) through (ix) of this section for those sterilization chambers;

(4) If emissions from any room in your facility are subject to an emission standard, you must report the ID for any room where there has not been the potential for EtO emissions since the end of the period covered by the previous compliance report. If a room has had the potential for EtO emissions since the end of the period covered by the previous compliance report, or if any of the information in paragraphs (b)(4)(i) through (vi) of this section has changed for a room where there is the potential for EtO emissions that was included in the previous compliance report, you must report the information in paragraphs (b)(4)(i) through (vi) of this section for those rooms;

(5) If an EtO CEMS was used to demonstrate continuous compliance, you must report the information specified in paragraphs (b)(5)(i) through (vi) of this section.

(6) If any portion of your facility is required to be operated with PTE, you must report the information listed in paragraph (b)(6) of this section.

(7) If you are complying with the requirement to follow the best management practice to limit sterilization chamber concentration of EtO to 1 ppmv prior to opening the sterilization chamber door, you must provide a certification from your responsible official that this approach is being followed and you are meeting the monitoring requirements at § 63.362(h).

(8) If you own or operate an existing collection of Group 2 room air emissions at an area source facility and facility EtO use is less than 4 tpy, you must report the ID for any room where Group 2 room air emissions have ceased since end of the period covered by the previous compliance report. If a room has had Group 2 room air emissions since the end of the period covered by the previous compliance report, or if any of the information in paragraphs (b)(8)(i) through (iv) of this section has changed for a room where there are Group 2 room air emissions that were included in the previous compliance report, you must report the information in paragraphs (b)(8)(i) through (iv) of this section for each room where there are Group 2 room air emissions.

(9) If you own or operate an existing collection of Group 2 room air emissions at an area source facility and facility EtO use is less than 4 tpy, you are not required to report the information in paragraph (c)(8) of this section if you meet the requirements in paragraph (b)(9) of this section.

(10) Report the number of deviations to meet an applicable standard. For each instance, report the date, time, the cause, and duration of each deviation. For each deviation, the report must include a list of the affected sources or equipment, the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to determine the emissions.

(d) *Construction and reconstruction application.* You must fulfill all requirements for construction or reconstruction of a facility in § 63.5, according to the applicability in table 6 to this subpart, and in this paragraph.

(1) *Applicability.* (i) This paragraph (d) and § 63.5 implement the preconstruction review requirements of section 112(i)(1) for facilities subject to these emissions standards. In addition, this paragraph (d) and § 63.5 include other requirements for constructed and reconstructed facilities that are or become subject to these emissions standards.

(ii) After April 5, 2024, the requirements in this section and in § 63.5 apply to owners or operators who construct a new facility or reconstruct a facility subject to these emissions standards after April 5, 2024. New or reconstructed facilities subject to these emissions standards with an initial startup date before the effective date are not subject to the preconstruction review requirements specified in paragraphs (b)(2) and (3) of this section and § 63.5(d)(3) and (4) and (e).

(2) *Advance approval.* After April 5, 2024, whether or not an approved permit program is effective in the jurisdictional authority in which a facility is (or would be) located, no person may construct a new facility or reconstruct a facility subject to these emissions standards, or reconstruct a facility such that the facility becomes a facility subject to these emissions standards, without obtaining advance written approval from the Administrator in accordance with the procedures specified in paragraph (b)(3) of this section and § 63.5(d)(3) and (4) and (e).

(3) *Application for approval of construction or reconstruction.* The provisions of paragraph (b)(3) of this section and § 63.5(d)(3) and (4) implement section 112(i)(1) of the Act.

(i) *General application requirements.* (A) An owner or operator who is subject to the requirements of paragraph (b)(2) of this section shall submit to the Administrator an application for approval of the construction of a new facility subject to these emissions standards, the reconstruction of a facility subject to these emissions standards, or the reconstruction of a facility such that the facility becomes a facility subject to these emissions standards. The application shall be submitted as soon as practicable before the construction or reconstruction is planned to commence (but not sooner than the effective date) if the construction or reconstruction commences after the effective date. The application shall be submitted as soon as practicable before the initial startup date but no later than 60 days after the effective date if the construction or reconstruction had commenced and the initial startup date had not occurred before the effective date. The application for approval of construction or reconstruction may be used to fulfill the initial notification requirements of paragraph (e)(1)(iii) of this section. The owner or operator may submit the application for approval well in advance of the date construction or reconstruction is planned to commence in order to ensure a timely review by the Administrator and that the planned commencement date will not be delayed.

(B) A separate application shall be submitted for each construction or reconstruction. Each application for approval of construction or reconstruction shall include at a minimum:

(*1*) The applicant's name and address.

(*2*) A notification of intention to construct a new facility subject to these emissions standards or make any physical or operational change to a facility subject to these emissions standards that may meet or has been determined to meet the criteria for a reconstruction, as defined in § 63.2.

(*3*) The address (*i.e.,* physical location) or proposed address of the facility.

(*4*) An identification of the relevant standard that is the basis of the application.

(*5*) The expected commencement date of the construction or reconstruction.

(*6*) The expected completion date of the construction or reconstruction.

(*7*) The anticipated date of (initial) startup of the facility.

(*8*) The type and quantity of hazardous air pollutants emitted by the facility, reported in units and averaging times and in accordance with the test methods specified in the standard, or if actual emissions data are not yet available, an estimate of the type and quantity of hazardous air pollutants expected to be emitted by the facility reported in units and averaging times specified. The owner or operator may submit percent reduction information, if the standard is established in terms of percent reduction. However, operating parameters, such as flow rate, shall be included in the submission to the extent that they demonstrate performance and compliance.

(*9*) Other information as specified in paragraph (b)(3)(ii) of this section and § 63.5(d)(3).

(C) An owner or operator who submits estimates or preliminary information in place of the actual emissions data and analysis required in paragraphs (b)(3)(i)(B)(*8*) and (b)(3)(ii) of this section shall submit the actual, measured emissions data and other correct information as soon as available but no later than with the notification of compliance status required in paragraph (c)(2) of this section.

(ii) *Application for approval of construction.* Each application for approval of construction shall include, in addition to the information required in paragraph (b)(3)(i)(B) of this section, technical information describing the proposed nature, size, design, operating design capacity, and method of

operation of the facility subject to these emissions standards, including an identification of each point of emission for each hazardous air pollutant that is emitted (or could be emitted) and a description of the planned air pollution control system (equipment or method) for each emission point. The description of the equipment to be used for the control of emissions shall include each control device for each hazardous air pollutant and the estimated control efficiency (percent) for each control device. The description of the method to be used for the control of emissions shall include an estimated control efficiency (percent) for that method. Such technical information shall include calculations of emission estimates in sufficient detail to permit assessment of the validity of the calculations. An owner or operator who submits approximations of control efficiencies under paragraph (b)(3) of this section shall submit the actual control efficiencies as specified in paragraph (b)(3)(i)(C) of this section.

(4) *Approval of construction or reconstruction based on prior jurisdictional authority preconstruction review.* (i) The Administrator may approve an application for construction or reconstruction specified in paragraphs (b)(2) and (3) of this section and § 63.5(d)(3) and (4) if the owner or operator of a new or reconstructed facility who is subject to such requirement demonstrates to the Administrator's satisfaction that the following conditions have been (or will be) met:

(A) The owner or operator of the new or reconstructed facility subject to these emissions standards has undergone a preconstruction review and approval process in the jurisdictional authority in which the facility is (or would be) located before the effective date and has received a federally enforceable construction permit that contains a finding that the facility will meet these emissions standards as proposed, if the facility is properly built and operated;

(B) In making its finding, the jurisdictional authority has considered factors substantially equivalent to those specified in § 63.5(e)(1).

(ii) The owner or operator shall submit to the Administrator the request for approval of construction or reconstruction no later than the application deadline specified in paragraph (b)(3)(i) of this section. The owner or operator shall include in the request information sufficient for the Administrator's determination. The Administrator will evaluate the owner or operator's request in accordance with the procedures specified in § 63.5. The Administrator may request additional relevant information after the submittal of a request for approval of construction or reconstruction.

(e) *Notification requirements.* The owner or operator of an affected source subject to an emissions standard in § 63.362 shall fulfill all notification requirements in § 63.9, according to the applicability in table 6 to this subpart, and in this paragraph (e).

(1) *Initial notifications.* (i) If you own or operate an affected source subject to an emissions standard in § 63.362, you may use the application for approval of construction or reconstruction under paragraph (d)(3)(ii) of this section and § 63.5(d)(3), respectively, if relevant to fulfill the initial notification requirements.

(ii) The owner or operator of a new or reconstructed facility subject to these emissions standards that has an initial startup date after the effective date and for which an application for approval of construction or reconstruction is required under paragraph (d)(3) of this section and § 63.5(d)(3) and (4) shall provide the following information in writing to the Administrator:

(A) A notification of intention to construct a new facility subject to these emissions standards, reconstruct a facility subject to these emissions standards, or reconstruct a facility such that the facility becomes a facility subject to these emissions standards with the application for approval of construction or reconstruction as specified in paragraph (d)(3)(i)(A) of this section;

(B) A notification of the date when construction or reconstruction was commenced, submitted simultaneously with the application for approval of construction or reconstruction, if construction or reconstruction was commenced before the effective date of these standards;

(C) A notification of the date when construction or reconstruction was commenced, delivered or postmarked no later than 30 days after such date, if construction or reconstruction was commenced after the effective date of these standards;

(D) A notification of the anticipated date of startup of the facility, delivered or postmarked not more than 60 days nor less than 30 days before such date; and

(E) A notification of the actual date of initial startup of the facility, delivered or postmarked within 15 calendar days after that date.

(iii) After the effective date, whether or not an approved permit program is effective in the jurisdictional authority in which a facility subject to these emissions standards is (or would be) located, an owner or operator who intends to construct a new facility subject to these emissions standards or reconstruct a facility subject to these emissions standards, or reconstruct a facility such that it becomes a facility subject to these emissions standards, shall notify the Administrator in writing of the intended construction or reconstruction. The notification shall be submitted as soon as practicable before the construction or reconstruction is planned to commence (but no sooner than the effective date of these standards) if the construction or reconstruction commences after the effective date of the standard. The notification shall be submitted as soon as practicable before the initial startup date but no later than 60 days after the effective date of this standard if the construction or reconstruction had commenced and the initial startup date has not occurred before the standard's effective date. The notification shall include all the information required for an application for approval of construction or reconstruction as specified in paragraph (d)(3) of this section and § 63.5(d)(3) and (4). For facilities subject to these emissions standards, the application for approval of construction or reconstruction may be used to fulfill the initial notification requirements of § 63.9.

(2) If an owner or operator of a facility subject to these emissions standards submits estimates or preliminary information in the application for approval of construction or reconstruction required in paragraph (d)(3)(ii) of this section and § 63.5(d)(3), respectively, in place of the actual emissions data or control efficiencies required in paragraphs (d)(3)(i)(B)(*8*) and (b)(3)(ii) of this section, the owner or operator shall submit the actual emissions data and other correct information as soon as available but no later than with the initial notification of compliance status.

(3) If you own or operate an affected source subject to an emissions standard in § 63.362, you must also include the amount of EtO used at the facility during the previous consecutive 12-month period in the initial notification report required by § 63.9(b)(2) and (3). For new sterilization facilities subject to this subpart, the amount of EtO used at the facility shall be an estimate of expected use during the first consecutive 12-month period of operation.

(4) Beginning October 7, 2024, you must submit all subsequent Notification of Compliance Status reports in PDF formatto the EPA following the

procedure specified in § 63.9(k), except any medium submitted through mail must be sent to the attention of the Commercial Sterilization Sector Lead.

(f) *Performance test submission.* Beginning on June 4, 2024, within 60 days after the date of completing each performance test required by this subpart, you must submit the results of the performance test following the procedures specified in paragraphs (f)(1) through (3) of this section.

(1) *Data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT website (https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert) at the time of the test.* Submit the results of the performance test to the EPA via the CEDRI, which can be accessed through the EPA's CDX (*https://cdx.epa.gov/*). The data must be submitted in a file format generated using the EPA's ERT. Alternatively, you may submit an electronic file consistent with the XML schema listed on the EPA's ERT website.

(2) *Data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the test.* The results of the performance test must be included as an attachment in the ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the ERT generated package or alternative file to the EPA via CEDRI.

(3) *CBI.* Do not use CEDRI to submit information you claim as CBI. Anything submitted using CEDRI cannot later be claimed CBI. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim for some of the information submitted under paragraph (f)(1)(i) or (ii) of this section, you must submit a complete file, including information claimed to be CBI, to the EPA. The file must be generated using the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described in paragraphs (f)(1)(i) and (ii) of this section. All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available.

(g) *Performance evaluation submission.* Beginning on June 4, 2024, within 60 days after the date of completing each CEMS performance evaluation (as defined in § 63.2), you must submit the results of the performance evaluation following the procedures specified in paragraphs (g)(1) through (3) of this section.

(1) *Performance evaluations of CEMS measuring relative accuracy test audit (RATA) pollutants that are supported by the EPA's ERT as listed on the EPA's ERT website at the time of the evaluation.* Submit the results of the performance evaluation to the EPA via CEDRI, which can be accessed through the EPA's CDX. The data must be submitted in a file format generated using the EPA's ERT. Alternatively, you may submit an electronic file consistent with the XML schema listed on the EPA's ERT website.

(2) *Performance evaluations of CEMS measuring RATA pollutants that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the evaluation.* The results of the performance evaluation must be included as an attachment in the ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the ERT generated package or alternative file to the EPA via CEDRI.

(3) *CBI.* Do not use CEDRI to submit information you claim as CBI. Anything submitted using CEDRI cannot later be claimed CBI. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim for some of the information submitted under paragraph (g)(1)(i) or (ii) of this section, you must submit a complete file, including information claimed to be CBI, to the EPA. The CBI file must be generated using the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the CBI file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described in paragraphs (g)(1)(i) and (ii) of this section. All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available.

(h) *Extensions for CDX/CEDRI outages.* If you are required to electronically submit a report through CEDRI in the EPA's CDX, you may assert a claim of EPA system outage for failure to timely comply with that reporting requirement. To assert a claim of EPA system outage, you must meet the requirements outlined in paragraphs (h)(1) through (7) of this section.

(1) You must have been or will be precluded from accessing CEDRI and submitting a required report within the time prescribed due to an outage of either the EPA's CEDRI or CDX systems.

(2) The outage must have occurred within the period of time beginning five business days prior to the date that the submission is due.

(3) The outage may be planned or unplanned.

(4) You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or has caused a delay in reporting.

(5) You must provide to the Administrator a written description identifying:

(i) The date(s) and time(s) when CDX or CEDRI was accessed and the system was unavailable;

(ii) A rationale for attributing the delay in reporting beyond the regulatory deadline to EPA system outage;

(iii) A description of measures taken or to be taken to minimize the delay in reporting; and

(iv) The date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported.

(6) The decision to accept the claim of EPA system outage and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(7) In any circumstance, the report must be submitted electronically as soon as possible after the outage is resolved.

(i) *Extensions for force majeure events.* If you are required to electronically submit a report through CEDRI in the EPA's CDX, you may assert a claim of *force majeure* for failure to timely comply with that reporting requirement. To assert a claim of *force majeure,* you must meet the requirements outlined in paragraphs (i)(1) through (5) of this section.

(1) You may submit a claim if a *force majeure* event is about to occur, occurs, or has occurred or there are lingering effects from such an event within the period of time beginning five business days prior to the date the submission is due. For the purposes of this section, a *force majeure* event is defined as an event that will be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevents you from complying with the requirement to submit a report electronically within the time period prescribed. Examples of such events are acts of nature (*e.g.,* hurricanes, earthquakes, or floods), acts of war or terrorism, or equipment failure or safety hazard beyond the control of the affected facility (*e.g.,* large scale power outage).

(2) You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or has caused a delay in reporting.

(3) You must provide to the Administrator:

(i) A written description of the *force majeure* event;

(ii) A rationale for attributing the delay in reporting beyond the regulatory deadline to the *force majeure* event;

(iii) A description of measures taken or to be taken to minimize the delay in reporting; and

(iv) The date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported.

(4) The decision to accept the claim of *force majeure* and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(5) In any circumstance, the reporting must occur as soon as possible after the force majeure event occurs.

§ 63.367 Recordkeeping requirements.

(a) If you own or operate an affected source subject to § 63.362, you must comply with the recordkeeping requirements in § 63.10(a) through (c), according to the applicability in table 6 to this subpart, and in this section. All records required to be maintained by this subpart or a subpart referenced by this subpart shall be maintained in such a manner that they can be readily accessed and are suitable for inspection.

(b) You must maintain the previous five years of records specified in § 63.366(b) and (c), as applicable.

(c) You must maintain the previous five years of records for compliance tests and associated data analysis, as applicable.

(d) Any records required to be maintained by this subpart that are submitted electronically via the EPA's CEDRI may be maintained in electronic format. This ability to maintain electronic copies does not affect the requirement for facilities to make records, data, and reports available upon request to a delegated air agency or the EPA as part of an on-site compliance evaluation.

(e) If you are using an EtO CEMS to demonstrate continuous compliance, you must maintain the previous five years of records for all required certification and QA tests.

(f) For each deviation from an emission limit, operating limit, or best management practice, you must keep a record of the information specified in paragraph (g)(1) through (4) of this section. The records shall be maintained as specified in § 63.10(b)(1).

(1) The occurrence and duration of each startup, shutdown, or malfunction of process, air pollution control, and monitoring equipment.

(2) In the event that an affected unit does not meet an applicable standard, record the number of deviations. For each deviation, record the date, time, cause, and duration of each deviation.

(3) For each failure to meet an applicable standard, record and retain a list of the affected sources or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit and a description of the method used to estimate the emissions.

(4) Record actions taken to minimize emissions in accordance with § 63.362(k) and any corrective actions taken to return the affected unit to its normal or usual manner of operation.

§ 63.368 Implementation and enforcement.

(a) This subpart can be implemented and enforced by the U.S. EPA or a delegated authority such as the applicable State, local, or Tribal agency. If the U.S. EPA Administrator has delegated authority to a State, local, or Tribal agency, then that agency, in addition to the U.S. EPA, has the authority to implement and enforce this subpart. Contact the applicable U.S. EPA Regional Office to find out whether implementation and enforcement of this subpart are delegated to a State, local, or Tribal agency.

(b) In delegating implementation and enforcement authority of this subpart to a State, local, or Tribal agency under subpart E of this part, the authorities contained in paragraph (c) of this section are retained by the Administrator of U.S. EPA and cannot be transferred to the State, local, or Tribal agency.

(c) The authorities that cannot be delegated to State, local, or Tribal agencies are as specified in paragraphs (c)(1) through (5) of this section.

(1) Approval of alternatives to the requirements in §§ 63.360 and 63.362.

(2) Approval of major alternatives to test methods under § 63.7(e)(2)(ii) and (f), as defined in § 63.90, and as required in this subpart.

(3) Approval of major alternatives to monitoring under § 63.8(f), as defined in § 63.90, and as required in this subpart.

(4) Approval of major alternatives to recordkeeping and reporting under § 63.10(f), as defined in § 63.90, and as required in this subpart.

(5) Approval of an alternative to any electronic reporting to the EPA required by this subpart.

Table 1 to Subpart O of Part 63—Standards for SCVs

As required in § 63.362(c), for each SCV, you must meet the applicable standard in the following table:

For each . . .	For which . . .	You must . . .	You must comply with the standard . . .
1. Existing SCV	a. Facility EtO use is at least 10 tpy	i. Continuously reduce EtO emissions by 99 percent [1].	Until April 6, 2026.
	b. Facility EtO use is at least 1 tpy but less than 10 tpy	i. Continuously reduce EtO emissions by 99 percent [1].	Until April 6, 2026.
		ii. Continuously reduce EtO emissions by 99.8 percent [2 3].	No later than April 6, 2026.
	c. Facility EtO use is at least 30 tpy	i. Continuously reduce EtO emissions by 99.99 percent [2 3].	No later than April 6, 2026.
	d. Facility EtO use is at least 10 tpy but less than 30 tpy	i. Continuously reduce EtO emissions by 99.9 percent [2 3].	No later than April 6, 2026.
	e. Facility EtO use is less than 1 tpy	i. Continuously reduce EtO emissions by 99 percent [2 4].	No later than April 5, 2027.

For each . . .	For which . . .	You must . . .	You must comply with the standard . . .
2. New SCV	a. Initial startup is on or before April 5, 2024, and facility EtO use is at least 30 tpy.	i. Continuously reduce EtO emissions by 99.99 percent[2][5].	No later than April 5, 2024.
	b. Initial startup is on or before April 5, 2024, and facility EtO use is at least 10 tpy but less than 30 tpy.	i. Continuously reduce EtO emissions by 99.9 percent[2][5].	No later than April 5, 2024.
	c. Initial startup is on or before April 5, 2024, and facility EtO use is at least 1 tpy but less than 10 tpy.	i. Continuously reduce EtO emissions by 99.8 percent[2][5].	No later than April 5, 2024.
	d. Initial startup is on or before April 5, 2024, and facility EtO use is less than 1 tpy.	i. Continuously reduce EtO emissions by 99 percent[2][6].	No later than April 5, 2024.
	e. Initial startup is after April 5, 2024, and facility EtO use is at least 30 tpy.	i. Continuously reduce EtO emissions by 99.99 percent[2][5].	Upon startup of the source.
	f. Initial startup is after April 5, 2024, and facility EtO use is at least 10 tpy but less than 30 tpy.	i. Continuously reduce EtO emissions by 99.9 percent[2][5].	Upon startup of the source.
	g. Initial startup is after April 5, 2024, and facility EtO use is at least 1 tpy but less than 10 tpy.	i. Continuously reduce EtO emissions by 99.8 percent[2][5].	Upon startup of the source.
	h. Initial startup is after April 5, 2024, and facility EtO use is less than 1 tpy.	i. Continuously reduce EtO emissions by 99 percent[2][6].	Upon startup of the source.

[1] The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after December 6, 1996.
[2] If using EtO CEMS to determine compliance, this standard is based on the previous 30 operating days of data.
[3] The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after April 7, 2025.
[4] The standard applies if the facility has used less than 1 tpy of EtO within all consecutive 12-month periods after April 6, 2026.
[5] The standard applies if the facility is expected to meet or exceed the specified EtO use within one year after startup. Afterwards, the standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after startup.
[6] The standard applies if the facility is not expected to meet or exceed 1 tpy of EtO use within one year after startup. Afterwards, the standard applies if the facility has used less than 1 tpy of EtO within all consecutive 12-month periods after startup.

Table 2 to Subpart O of Part 63—Standards for ARVs

As required in § 63.362(d), for each ARV, you must meet the applicable standard in the following table:

For each . . .	For which . . .	You must . . .	You must comply with the standard . . .
1. Existing ARV	a. Facility EtO use is at least 10 tpy	i. Continuously reduce EtO emissions by 99 percent[1].	Until April 6, 2026.
	b. Facility EtO use is at least 30 tpy	i. Continuously reduce EtO emissions by 99.9 percent[2][3].	No later than April 6, 2026.
	c. Facility EtO use is at least 10 tpy but less than 30 tpy	i. Continuously reduce EtO emissions by 99.6 percent[2][3].	No later than April 6, 2026.
	d. Facility EtO use is less than 10 tpy	i. Continuously reduce EtO emissions by 99 percent[2][4].	No later than April 5, 2027.
2. New ARV	a. Initial startup is on or before April 5, 2024, and facility EtO use is at least 10 tpy.	i. Continuously reduce EtO emissions by 99.9 percent[2][5].	No later than April 5, 2024.
	b. Initial startup is on or before April 5, 2024, and facility EtO use is less than 10 tpy.	i. Continuously reduce EtO emissions by 99 percent[2][6].	No later than April 5, 2024.
	c. Initial startup is after April 5, 2024, and facility EtO use is at least 10 tpy.	i. Continuously reduce EtO emissions by 99.9 percent[2][5].	Upon startup of the source.
	d. Initial startup is after April 5, 2024, and facility EtO use is less than 10 tpy.	i. Continuously reduce EtO emissions by 99 percent[2][6].	Upon startup of the source.

[1] The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after December 6, 1996.
[2] If using CEMS to determine compliance, this standard is based on a rolling 30-operating day average.
[3] The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after April 7, 2025.
[4] The standard applies if the facility has used less than 10 tpy of EtO within all consecutive 12-month periods after April 6, 2026.
[5] The standard applies if the facility is expected to meet or exceed the specified EtO use within one year after startup. Afterwards, the standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after startup.
[6] The standard applies if the facility is not expected to meet or exceed 10 tpy of EtO use within one year after startup. Afterwards, the standard applies if the facility has used less than 10 tpy of EtO within all consecutive 12-month periods after startup.

Table 3 to Subpart O of Part 63—Standards for CEVs

As required in § 63.362(e), for each CEV, you must meet the applicable standard in the following table:

For each . . .	For which . . .	You must . . .	You must comply with the standard . . .
1. Existing CEV at a major source facility.	a. Not applicable	i. Continuously reduce EtO emissions by 99.94 percent[1].	No later than April 5, 2027.
2. Existing CEV at an area source facility.	a. Facility EtO use is at least 60 tpy	i. Continuously reduce EtO emissions by 99.9 percent[1][2].	No later than April 6, 2026.
	b. Facility EtO use is less than 60 tpy	i. Continuously reduce EtO emissions by 99 percent[1][3].	No later than April 5, 2027.
3. New CEV at a major source facility.	a. Initial startup is on or before April 5, 2024	i. Continuously reduce EtO emissions by 99.94 percent[1].	No later than April 5, 2024.

For each . . .	For which . . .	You must . . .	You must comply with the standard . . .
	b. Initial startup is after April 5, 2024	i. Continuously reduce EtO emissions by 99.94 percent [1].	Upon startup of the source.
4. New CEV at an area source facility.	a. Initial startup is on or before April 5, 2024, and facility EtO use is at least 60 tpy.	i. Continuously reduce EtO emissions by 99.9 percent [1 4].	No later than April 5, 2024.
	b. Initial startup is on or before April 5, 2024, facility EtO use is less than 60 tpy.	i. Continuously reduce EtO emissions by 99 percent [1 5].	No later than April 5, 2024.
	c. Initial startup is after April 5, 2024, and facility EtO use is at least 60 tpy.	i. Continuously reduce EtO emissions by 99.9 percent [1 4].	Upon startup of the source.
	d. Initial startup is after April 5, 2024, facility EtO use is less than 60 tpy.	i. Continuously reduce EtO emissions by 99 percent [1 5].	Upon startup of the source.

[1] If using CEMS to determine compliance, this standard is based on a rolling 30-operating day average.
[2] The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after April 7, 2025.
[3] The standard applies if the facility has used less than 60 tpy of EtO within all consecutive 12-month periods after April 6, 2026.
[4] The standard applies if the facility is expected to meet or exceed the specified EtO use within one year after startup. Afterwards, the standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after startup.
[5] The standard applies if the facility is not expected to meet or exceed 60 tpy of EtO use within one year after startup. Afterwards, the standard applies if the facility has used less than 60 tpy of EtO within all consecutive 12-month periods after startup.

Table 4 to Subpart O of Part 63—Standards for Group 1 Room Air Emissions

As required in § 63.362(f), for your collection of Group 1 room air emissions at each facility, you must meet the applicable standard in the following table:

For each . . .	For which . . .	You must . . .	You must comply with the requirement(s) . . .
1. Existing collection of Group 1 room air emissions at a major source facility.	a. Not applicable	i. Operate all areas of the facility that contain Group 1 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system. Also,	No later than April 5, 2027.
		ii. Continuously reduce EtO emissions by 97 percent [1]	
2. Existing collection of Group 1 room air emissions at an area source facility.	a. Facility EtO use is at least 40 tpy.	i. Operate all areas of the facility that contain Group 1 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system.[2] Also,	No later than April 6, 2026.
		ii. Continuously reduce EtO emissions by 98 percent [1 2]	
	b. Facility EtO use is less than 40 tpy.	i. Operate all areas of the facility that contain Group 1 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system. Also,	No later than April 5, 2027.
		ii. Continuously reduce EtO emissions by 80 percent [1 3]	
3. New collection of Group 1 room air emissions at a major source facility.	a. Initial startup is on or before April 5, 2024.	i. Operate all areas of the facility that contain Group 1 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system. Also,	No later than April 5, 2024.
		ii. Continuously reduce EtO emissions by 97 percent [1]	
	b. Initial startup is after April 5, 2024.	i. Operate all areas of the facility that contain Group 1 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system. Also,	Upon startup of the source.
		ii. Continuously reduce EtO emissions by 97 percent [1]	
4. New collection of Group 1 room air emissions at an area source facility.	a. Initial startup is on or before April 5, 2024, and facility EtO use is at least 40 tpy.	i. Operate all areas of the facility that contain Group 1 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system.[4] Also,	No later than April 5, 2024.
		ii. Continuously reduce EtO emissions by 98 percent [1 4]	
	b. Initial startup is on or before April 5, 2024, and facility EtO use is less than 40 tpy.	i. Operate all areas of the facility that contain Group 1 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system.[5] Also,	No later than April 5, 2024.
		ii. Continuously reduce EtO emissions by 80 percent [1 5]	
	c. Initial startup is after April 5, 2024, and facility EtO use is at least 40 tpy.	i. Operate all areas of the facility that contain Group 1 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system.[4] Also,	Upon startup of the source.
		ii. Continuously reduce EtO emissions by 98 percent [1 4]	
	d. Initial startup is after April 5, 2024, and facility EtO use is less than 40 tpy.	i. Operate all areas of the facility that contain Group 1 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system.[5] Also,	Upon startup of the source.
		ii. Continuously reduce EtO emissions by 80 percent [1 5]	

[1] If using CEMS to determine compliance, this standard is based on a rolling 30-operating day average.
[2] The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after April 7, 2025.
[3] The standard applies if the facility has used less than 40 tpy of EtO within all consecutive 12-month periods after April 6, 2026.
[4] The standard applies if the facility is expected to meet or exceed the specified EtO use within one year after startup. Afterwards, the standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after startup.
[5] The standard applies if the facility is not expected to meet or exceed 40 tpy of EtO use within one year after startup. Afterwards, the standard applies if the facility has used less than 40 tpy of EtO within all consecutive 12-month periods after startup.

Table 5 to Subpart O of Part 63—Standards for Group 2 Room Air Emissions

As required in § 63.362(g), for your collection of Group 2 room air emissions, you must meet the applicable standard in the following table:

For each . . .	For which . . .	You must . . .	You must comply with the requirement(s) . . .
1. Existing collection of Group 2 room air emissions at a major source facility.	a. Not applicable	i. Operate all areas of the facility that contain Group 2 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system. Also, ii. Continuously reduce EtO emissions by 86 percent [1]	No later than April 5, 2027.
2. Existing collection of Group 2 room air emissions at an area source facility.	a. Facility EtO use is at least 20 tpy.	i. Operate all areas of the facility that contain Group 2 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system.[2] Also,. ii. Continuously reduce EtO emissions by 98 percent [1 2]	No later than April 6, 2026.
	b. Facility EtO use is at least 4 tpy but less than 20 tpy.	i. Operate all areas of the facility that contain Group 2 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system.[2] Also, ii. Continuously reduce EtO emissions by 80 percent [1 2]	No later than April 6, 2026.
	c. Facility EtO use is less than 4 tpy.	Lower the EtO concentration within each sterilization chamber to 1 ppm before the chamber can be opened [3].	No later than April 5, 2027.
3. New collection of Group 2 room air emissions at a major source facility.	a. Initial startup is on or before April 5, 2024.	i. Operate all areas of the facility that contain Group 2 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system. Also, ii. Continuously reduce EtO emissions by 86 percent [1]	No later than April 5, 2024.
	b. Initial startup is after April 5, 2024.	i. Operate all areas of the facility that contain Group 2 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system. Also, ii. Continuously reduce EtO emissions by 86 percent [1]	Upon startup of the source.
4. New collection of Group 2 room air emissions at an area source facility.	a. Initial startup is on or before April 5, 2024, and facility EtO use is at least 20 tpy.	i. Operate all areas of the facility that contain Group 2 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system.[5] Also, ii. Continuously reduce EtO emissions by 98 percent [1 5]	No later than April 5, 2024.
	b. Initial startup is on or before April 5, 2024, and facility EtO use is less than 20 tpy.	i. Operate all areas of the facility that contain Group 2 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system.[6] Also, ii. Continuously reduce EtO emissions by 80 percent [1 6]	No later than April 5, 2024.
	c. Initial startup is after April 5, 2024, and facility EtO use is at least 20 tpy.	i. Operate all areas of the facility that contain Group 2 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system.[5] Also, ii. Continuously reduce EtO emissions by 98 percent [1 5]	Upon startup of the source.
	d. Initial startup is after April 5, 2024, and facility EtO use is less than 20 tpy.	i. Operate all areas of the facility that contain Group 2 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system.[6] Also, ii. Continuously reduce EtO emissions by 80 percent [1 6]	Upon startup of the source.

[1] This standard is based on a rolling 30-operating day average.
[2] The standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after April 7, 2025.
[3] The standard applies if the facility has used less than 4 tpy of EtO within all consecutive 12-month periods after April 6, 2026.
[4] The standard applies if the facility is expected to meet or exceed the specified EtO use within one year after startup. Afterwards, the standard applies if the facility has met or exceeded the specified EtO use within any consecutive 12-month period after startup.
[5] The standard applies if the facility is not expected to meet or exceed 20 tpy of EtO use within one year after startup. Afterwards, the standard applies if the facility has used less than 20 tpy of EtO within all consecutive 12-month periods after startup.

Table 6 to Subpart O of Part 63—Applicability of General Provisions to This Subpart

As specified in § 63.360, the parts of the General Provisions that apply to you are shown in the following table:

Citation	Subject	Applies to subpart O
§ 63.1(a)(1)	Applicability	Yes, additional terms defined in § 63.361; when overlap between subparts A and O occurs, subpart O takes precedence.
§ 63.1(a)(2)–(3)		Yes.
§ 63.1(a)(4)		Yes. Subpart O clarifies the applicability of each paragraph in subpart A to facilities subject to subpart O.
§ 63.1(a)(5)	[Reserved]	No.
§ 63.1(a)(6)–(8)		Yes.
§ 63.1(a)(9)	[Reserved].	
§ 63.1(a)(10)–(14)		Yes.
§ 63.1(b)(1)–(2)		Yes.
§ 63.1(b)(3)		No.
§ 63.1(c)(1)		No. Subpart O clarifies the applicability of each paragraph in subpart A to facilities subject to subpart O in this table.
§ 63.1(c)(2)		Yes.

Citation	Subject	Applies to subpart O
§ 63.1(c)(3)	[Reserved]	No.
§ 63.1(c)(4)		Yes.
§ 63.1(c)(5)		No. § 63.360 specifies applicability.
§ 63.1(c)(6)		Yes.
§ 63.1(d)	[Reserved]	No.
§ 63.1(e)		Yes.
§ 63.2	Definitions	Yes, additional terms defined in § 63.361; when overlap between subparts A and O occurs, subpart O takes precedence.
§ 63.3	Units and abbreviations	Yes, other units used in subpart O are defined in the text of subpart O.
§ 63.4(a)(1)–(3)	Prohibited activities	Yes.
§ 63.5(a)	Construction/Reconstruction	No. § 63.366(b)(1) contains applicability requirements for constructed or reconstructed facilities.
§ 63.5(b)(1)		Yes.
§ 63.5(b)(2)	[Reserved].	
§ 63.5(b)(3)		No. See § 63.366(b)(2).
§ 63.5(b)(4)–(6)		Yes.
§ 63.5(c)	[Reserved].	
§ 63.5(d)(1)–(2)		No. See § 63.366(b)(3).
§ 63.5(d)(3)–(4)		Yes.
§ 63.5(e)		Yes.
§ 63.5(f)(1)–(2)		No. See § 63.366(b)(4).
§ 63.6(a)	Applicability	Yes.
§ 63.6(b)–(c)		No. § 63.360(j) specifies compliance dates for facilities.
§ 63.6(d)	[Reserved].	
§ 63.6(e)(1)(i)		No.
§ 63.6(e)(1)(ii)	Requirement to correct malfunctions ASAP.	No.
§ 63.6(e)(1)(iii)		Yes.
§ 63.6(e)(2)	[Reserved]	No.
§ 63.6(e)(3)	SSM Plan Requirements	No.
§ 63.6(f)(1)	SSM exemption	No.
§ 63.6(f)(2)(i)	Methods for Determining Compliance.	Yes.
§ 63.6(f)(2)(ii)		No. § 63.363 specifies parameters for determining compliance.
§ 63.6(f)(2)(iii)–(iv)		Yes.
§ 63.6(f)(2)(v)		No.
§ 63.6(f)(3)		Yes.
§ 63.6(g)	Alternative Standard	Yes.
§ 63.6(h)	Compliance with opacity and visible emission standards.	No. Subpart O does not contain any opacity or visible emission standards.
§ 63.6(i)(1)–(14), and (16)	Compliance Extension	Yes.
§ 63.6(j)	Presidential Compliance Exemption.	Yes.
§ 63.7(a)	Applicability and Performance Test Dates.	Yes.
§ 63.7(b)	Notification of Performance Test.	Yes.
§ 63.7(c)	Quality Assurance/Test Plan	Yes.
§ 63.7(d)	Testing Facilities	Yes.
§ 63.7(e)(1)	SSM exemption	No.
§ 63.7(e)(2)–(4)	Conduct of Performance Tests	Yes. § 63.365 also contains test methods specific to facilities subject to the emissions standards.
§ 63.7(f)	Alternative Test Method	Yes.
§ 63.7(g)	Performance Test Data Analysis.	Yes, except this subpart specifies how and when the performance test and performance evaluation results are reported.
§ 63.7(h)	Waiver of Tests	Yes.
§ 63.8(a)(1)	Applicability of Monitoring Requirements.	Yes.
§ 63.8(a)(2)	Performance Specifications	Yes.
§ 63.8(a)(3)	[Reserved]	No.
§ 63.8(a)(4)	Monitoring with Flares	Yes.
§ 63.8(b)(1)	Monitoring	Yes.
§ 63.8(b)(2)–(3)	Multiple Effluents and Multiple Monitoring Systems.	Yes.
§ 63.8(c)(1)(i)	General duty to minimize emissions and CMS operation.	No.
§ 63.8(c)(1)(ii)		No. A startup, shutdown, and malfunction plan is not required for these standards.
§ 63.8(c)(1)(iii)	Requirement to develop SSM Plan for CMS.	No.
§ 63.8(c)(2)–(3)		Yes.
§ 63.8(c)(4)–(5)		No. Frequency of monitoring measurements is provided in § 63.364; opacity monitors are not required for these standards.
§ 63.8(c)(6)		No. Performance specifications are contained in § 63.365.

Citation	Subject	Applies to subpart O
§ 63.8(c)(7)(i)(A)–(B)	.....	No. Performance specifications are contained in § 63.365.
§ 63.8(c)(7)(i)(C)	.....	No. Opacity monitors are not required for these standards.
§ 63.8(c)(7)(ii)	.....	No. Performance specifications are contained in § 63.365.
§ 63.8(c)(8)	.....	No.
§ 63.8(d)(1)–(2)	.....	Yes.
§ 63.8(d)(3)	Written procedures for CMS	No.
§ 63.8(e)(1)	CMS Performance Evaluation	Yes, but only applies for CEMS, except this subpart specifies how and when the performance evaluation results are reported.
§ 63.8(e)(2)	.....	Yes.
§ 63.8(e)(3)	.....	Yes.
§ 63.8(e)(4)	.....	Yes.
§ 63.8(e)(5)(i)	.....	Yes.
§ 63.8(e)(5)(ii)	.....	No. Opacity monitors are not required for these standards.
§ 63.8(f)(1)–(5)	.....	Yes.
§ 63.8(f)(6)	.....	No.
§ 63.8(g)(1)	.....	Yes.
§ 63.8(g)(2)	.....	No.
§ 63.8(g)(3)–(5)	.....	Yes.
§ 63.9(a)	Notification requirements	Yes.
§ 63.9(b)(1)–(i)	.....	Yes.
§ 63.9(b)(1)(ii)–(iii)	Initial Notifications	No. § 63.366(c)(1)(i) contains language for facilities that increase usage such that the source becomes subject to the emissions standards.
§ 63.9(b)(2)–(3)	Initial Notifications	Yes. § 63.366(c)(3) contains additional information to be included in the initial report for existing and new facilities.
§ 63.9(b)(4)–(5)	Initial Notifications	No. § 63.366(c)(1)(ii) and (iii) contains requirements for new or reconstructed facilities subject to the emissions standards.
§ 63.9(c)	Request for Compliance Extension.	Yes.
§ 63.9(d)	Notification of Special Compliance Requirements for New Sources.	No.
§ 63.9(e)	Notification of Performance Test.	Yes.
§ 63.9(f)	Notification of VE/Opacity Test	No. Opacity monitors are not required for these standards.
§ 63.9(g)(1)	Additional Notifications When Using CMS.	Yes.
§ 63.9(g)(2)–(3)	Additional Notifications When Using CMS.	No. Opacity monitors and relative accuracy testing are not required for these standards.
§ 63.9(h)(1)–(3)	Notification of Compliance Status.	Yes, except § 63.9(h)(5) does not apply because § 63.366(c)(2) instructs facilities to submit actual data.
§ 63.9(i)	Adjustment of Submittal Deadlines.	Yes.
§ 63.9(j)	Change in previous information	Yes.
§ 63.9(k)	Electronic reporting procedures	Yes, as specified in § 63.9(j).
§ 63.10(a)	Recordkeeping/Reporting	Yes.
§ 63.10(b)(1)	Recordkeeping/Reporting	Yes.
§ 63.10(b)(2)(i)	Recordkeeping for startup and shutdown.	No. See 63.367(f) for recordkeeping requirements.
§ 63.10(b)(2)(ii)	Recordkeeping for SSM and failures to meet standards.	No. See 63.367(f) for recordkeeping requirements.
§ 63.10(b)(2)(iii)	Records related to maintenance of air pollution control equipment.	Yes.
§ 63.10(b)(2)(iv)–(v)	Actions taken to minimize emissions during SSM.	No.
§ 63.10(b)(2)(vi)	CMS Records	Yes.
§ 63.10(b)(2)(vii)–(ix)	Records	Yes.
§ 63.10(b)(2)(x)–(xi)	CMS Records	Yes.
§ 63.10(b)(2)(xii)	Records	Yes.
§ 63.10(b)(2)(xiii)	Records	Yes.
§ 63.10(b)(2)(xiv)	Records	Yes.
§ 63.10(b)(3)	Records	Yes.
§ 63.10(c)(1)–(14)	Records	Yes.
§ 63.10(c)(15)	Use of SSM Plan	No.
§ 63.10(d)(1)	General Reporting Requirements.	Yes.
§ 63.10(d)(2)	Report of Performance Test Results.	No. This subpart specifies how and when the performance test results are reported.
§ 63.10(d)(3)	Reporting Opacity or VE Observations.	No. Subpart O does not contain opacity or visible emissions standards.
§ 63.10(d)(4)	Progress Reports	Yes.
§ 63.10(d)(5)	SSM Reports	No. See § 63.366 for malfunction reporting requirements.
§ 63.10(e)(1)	Additional CEMS Reports	Yes.

Citation	Subject	Applies to subpart O
§ 63.10(e)(2)(i)	Additional CMS Reports	Yes, except this subpart specifies how and when the performance evaluation results are reported.
§ 63.10(e)(2)(ii)	Additional COMS Reports	No. Opacity monitors are not required for these standards.
§ 63.10(e)(3)(i)–(iv)	Reports	Yes.
§ 63.10(e)(3)(v)	Excess Emissions Reports	No. § 63.366(b) and (c) specify contents and submittal dates for excess emissions and monitoring system performance reports.
§ 63.10(e)(3)(vi)–(viii)	Excess Emissions Report and Summary Report.	Yes.
§ 63.10(e)(4)	Reporting COMS data	No. Opacity monitors are not required for these standards.
§ 63.10(f)	Waiver for Recordkeeping/Reporting.	Yes.
§ 63.11	Control device requirements for flares and work practice requirements for equipment leaks.	Yes.
§ 63.12	Delegation	Yes.
§ 63.13	Addresses	Yes.
§ 63.14	Incorporation by Reference	Yes.
§ 63.15	Availability of Information	Yes.

Appendix A to Subpart O of Part 63—Monitoring Provisions for EtO CEMS

1. Applicability

These monitoring provisions apply to the measurement of EtO emissions from commercial sterilization facilities, using CEMS. The CEMS must be capable of measuring EtO in lb/hr.

2. Monitoring of EtO Emissions

2.1 *Monitoring System Installation Requirements.* Install EtO CEMS and any additional monitoring systems needed to convert pollutant concentrations to lb/hr in accordance with § 63.365 and Performance Specification 19 (PS 19) of appendix B to part 60 of this chapter.

2.2 *Primary and Backup Monitoring Systems.* In the electronic monitoring plan described in section 10.1.1.2.1 of this appendix, you must designate a primary EtO CEMS. The primary EtO CEMS must be used to report hourly EtO concentration values when the system is able to provide quality-assured data, *i.e.,* when the system is ''in control''. However, to increase data availability in the event of a primary monitoring system outage, you may install, operate, maintain, and calibrate backup monitoring systems, as follows:

2.2.1 *Redundant Backup Systems.* A redundant backup monitoring system is a separate EtO CEMS with its own probe, sample interface, and analyzer. A redundant backup system is one that is permanently installed at the unit or stack location and is kept on ''hot standby'' in case the primary monitoring system is unable to provide quality-assured data. A redundant backup system must be represented as a unique monitoring system in the electronic monitoring plan. Each redundant backup monitoring system must be certified according to the applicable provisions in section 3 of this appendix and must meet the applicable on-going QA requirements in section 5 of this appendix.

2.2.2 *Non-redundant Backup Monitoring Systems.* A non-redundant backup monitoring system is a separate EtO CEMS that has been certified at a particular unit or stack location but is not permanently installed at that location. Rather, the system is kept on ''cold standby'' and may be reinstalled in the event of a primary monitoring system outage. A nonredundant backup monitoring system must be represented as a unique monitoring system in the electronic monitoring plan. Non-redundant backup EtO CEMS must complete the same certification tests as the primary monitoring system, with one exception. The 7-day calibration error test is not required for a non-redundant backup EtO CEMS. Except as otherwise provided in section 2.2.4.4 of this appendix, a non-redundant backup monitoring system may only be used for 720 hours per year at a particular unit or stack location.

2.2.3 *Temporary Like-kind Replacement Analyzers.* When a primary EtO analyzer needs repair or maintenance, you may temporarily install a like-kind replacement analyzer, to minimize data loss. Except as otherwise provided in section 2.2.4.4 of this appendix, a temporary like-kind replacement analyzer may only be used for 720 hours per year at a particular unit or stack location. The analyzer must be represented as a component of the primary EtO CEMS and must be assigned a 3-character component ID number, beginning with the prefix ''LK''.

2.2.4 *Quality Assurance Requirements for Non-redundant Backup Monitoring Systems and Temporary Like-kind Replacement Analyzers.* To quality-assure the data from non-redundant backup EtO monitoring systems and temporary like-kind replacement EtO analyzers, the following provisions apply:

2.2.4.1 When a certified non-redundant backup EtO CEMS or a temporary like-kind replacement EtO analyzer is brought into service, a calibration error test and a linearity check must be performed and passed. A single point system integrity check is also required.

2.2.4.2 Each non-redundant backup EtO CEMS or temporary like-kind replacement EtO analyzer shall comply with all required daily, weekly, and quarterly quality-assurance test requirements in section 5 of this appendix, for as long as the system or analyzer remains in service.

2.2.4.3 For the routine, on-going quality-assurance of a non-redundant backup EtO monitoring system, a relative accuracy test audit (RATA) must be performed and passed at least once every 8 calendar quarters at the unit or stack location(s) where the system will be used.

2.2.4.4 To use a non-redundant backup EtO monitoring system or a temporary like-kind replacement analyzer for more than 720 hours per year at a particular unit or stack location, a RATA must first be performed and passed at that location.

2.3 *Monitoring System Equipment, Supplies, Definitions, and General Operation.*

The following provisions apply:

2.3.1 PS 19, Sections 3.0, 6.0, and 11.0 of appendix B to part 60 of this chapter.

3. Initial Certification Procedures

The initial certification procedures for the EtO CEMS used to provide data under this subpart are as follows:

3.1 Your EtO CEMS must be certified according to PS 19, section(s) 13.

3.2 Any additional stack gas flow rate monitoring system(s) needed to express pollutant concentrations in lb/hr must be certified according to part 75 of this chapter.

4. Recertification Procedures

Whenever the owner or operator makes a replacement, modification, or change to a certified CEMS that may significantly affect the ability of the system to accurately measure or record pollutant gas concentrations or stack gas flow rates, the owner or operator shall recertify the monitoring system. Furthermore, whenever the owner or operator makes a replacement, modification, or change to the flue gas handling system or the unit operation that may significantly change the concentration or flow profile, the owner or operator shall recertify the monitoring system. The same tests performed for the initial certification of the monitoring system shall be repeated for recertification, unless otherwise specified by the Administrator. Examples of changes that require recertification include: Replacement of a gas analyzer; complete monitoring

system replacement, and changing the location or orientation of the sampling probe.

5. On-Going Quality Assurance Requirements

On-going QA test requirements for EtO CEMS must be implemented as follows:

5.1 The quality assurance/quality control procedures in Procedure 7 of appendix F to part 60 of this chapter shall apply.

5.2 Stack gas flow rate, diluent gas, and moisture monitoring systems must meet the applicable ongoing QA test requirements of part 75 of this chapter.

5.2.1 *Out-of-Control Periods.* A EtO CEMS that is used to provide data under this appendix is considered to be out-of-control, and data from the CEMS may not be reported as quality-assured, when any acceptance criteria for a required QA test is not met. The EtO CEMS is also considered to be out-of-control when a required QA test is not performed on schedule or within an allotted grace period. To end an out-of-control period, the QA test that was either failed or not done on time must be performed and passed. Out-of-control periods are counted as hours of monitoring system downtime.

5.2.2 *Grace Periods.* For the purposes of this appendix, a ''grace period'' is defined as a specified number of unit or stack operating hours after the deadline for a required quality-assurance test of a continuous monitor has passed, in which the test may be performed and passed without loss of data.

5.2.2.1 For the flow rate monitoring systems described in section 5.1 of this appendix, a 168 unit or stack operating hour grace period is available for quarterly linearity checks, and a 720 unit or stack operating hour grace period is available for RATAs, as provided, respectively, in sections 2.2.4 and 2.3.3 of appendix B to part 75 of this chapter.

5.2.2.2 For the purposes of this appendix, if the deadline for a required gas audit or RATA of a EtO CEMS cannot be met due to circumstances beyond the control of the owner or operator:

5.2.2.2.1 A 168 unit or stack operating hour grace period is available in which to perform the gas audit; or

5.2.2.2.2 A 720 unit or stack operating hour grace period is available in which to perform the RATA.

5.2.2.3 If a required QA test is performed during a grace period, the deadline for the next test shall be determined as follows:

5.2.2.3.1 For the gas audit of an EtO CEMS, the grace period test only satisfies the audit requirement for the calendar quarter in which the test was originally due. If the calendar quarter in which the grace period audit is performed is a QA operating quarter, an additional gas audit is required for that quarter.

5.2.2.3.2 For the RATA of an EtO CEMS, the next RATA is due within three QA operating quarters after the calendar quarter in which the grace period test is performed.

5.2.3 *Conditional Data Validation.* For recertification and diagnostic testing of the monitoring systems that are used to provide data under this appendix, and for the required QA tests when nonredundant backup monitoring systems or temporary like-kind replacement analyzers are brought into service, the conditional data validation provisions in §§ 75.20(b)(3)(ii) through (b)(3)(ix) of this chapter may be used to avoid or minimize data loss. The allotted window of time to complete calibration tests and RATAs shall be as specified in § 75.20(b)(3)(iv) of this chapter; the allotted window of time to complete a gas audit shall be the same as for a linearity check (*i.e.,* 168 unit or stack operating hours).

5.3 *Data Validation.*

5.3.1 *Out-of-Control Periods.* An EtO CEMS that is used to provide data under this appendix is considered to be out-of-control, and data from the CEMS may not be reported as quality-assured, when any acceptance criteria for a required QA test is not met. The EtO CEMS is also considered to be out-of-control when a required QA test is not performed on schedule or within an allotted grace period. To end an out-of-control period, the QA test that was either failed or not done on time must be performed and passed. Out-of-control periods are counted as hours of monitoring system downtime.

5.3.2 *Grace Periods.* For the purposes of this appendix, a ''grace period'' is defined as a specified number of unit or stack operating hours after the deadline for a required quality-assurance test of a continuous monitor has passed, in which the test may be performed and passed without loss of data.

5.3.2.1 For the monitoring systems described in section 5.1 of this appendix, a 168 unit or stack operating hour grace period is available for quarterly linearity checks, and a 720 unit or stack operating hour grace period is available for RATAs, as provided, respectively, in sections 2.2.4 and 2.3.3 of appendix B to part 75 of this chapter.

5.3.2.2 For the purposes of this appendix, if the deadline for a required gas audit/data accuracy assessment or RATA of an EtO CEMS cannot be met due to circumstances beyond the control of the owner or operator:

5.3.2.2.1 A 168 unit or stack operating hour grace period is available in which to perform the gas audit or other quarterly data accuracy assessment; or

5.3.2.2.2 A 720 unit or stack operating hour grace period is available in which to perform the RATA.

5.3.2.3 If a required QA test is performed during a grace period, the deadline for the next test shall be determined as follows:

5.3.2.3.1 For a gas audit or RATA of the monitoring systems described in sections 5.1 and 5.2 of this appendix, determine the deadline for the next gas audit or RATA (as applicable) in accordance with section 2.2.4(b) or 2.3.3(d) of appendix B to part 75 of this chapter; treat a gas audit in the same manner as a linearity check.

5.3.2.3.2 For the gas audit or other quarterly data accuracy assessment of an EtO CEMS, the grace period test only satisfies the audit requirement for the calendar quarter in which the test was originally due. If the calendar quarter in which the grace period audit is performed is a QA operating quarter, an additional gas audit/data accuracy assessment is required for that quarter.

5.3.2.3.3 For the RATA of an EtO CEMS, the next RATA is due within three QA operating quarters after the calendar quarter in which the grace period test is performed.

5.3.3 *Conditional Data Validation.* For recertification and diagnostic testing of the monitoring systems that are used to provide data under this appendix, the conditional data validation provisions in § 75.20(b)(3)(ii) through (ix) of this chapter may be used to avoid or minimize data loss. The allotted window of time to complete calibration tests and RATAs shall be as specified in § 75.20(b)(3)(iv) of this chapter; the allotted window of time to complete a quarterly gas audit or data accuracy assessment shall be the same as for a linearity check (*i.e.,* 168 unit or stack operating hours).

6. Missing Data Requirements

For the purposes of this appendix, the owner or operator of an affected unit shall not substitute for missing data from EtO CEMS. Any process operating hour for which quality-assured EtO concentration data are not obtained is counted as an hour of monitoring system downtime.

7. Bias Adjustment

Bias adjustment of hourly emissions data from an EtO CEMS is not required.

8. QA/QC Program Requirements

The owner or operator shall develop and implement a quality assurance/quality control (QA/QC) program for the EtO CEMS that are used to provide data under this subpart. At a minimum, the program shall include a written plan that describes in detail (or that refers to separate documents containing) complete, step-by-step procedures and operations for the most important QA/QC activities. Electronic storage of the QA/QC plan is permissible, provided that the information can be made available in hard copy to auditors and inspectors. The QA/QC program requirements for the other monitoring systems described in section 5.2 of this appendix are specified in section 1 of appendix B to part 75 of this chapter.

8.1 *General Requirements for EtO CEMS.*

8.1.1 *Preventive Maintenance.* Keep a written record of procedures needed to maintain the EtO CEMS in proper operating condition and a schedule for those procedures. This shall, at a minimum, include procedures specified by the manufacturers of the equipment and, if applicable, additional or alternate procedures developed for the equipment.

8.1.2 *Recordkeeping and Reporting.* Keep a written record describing procedures that will be used to implement the recordkeeping and reporting requirements of this appendix.

8.1.3 *Maintenance Records.* Keep a record of all testing, maintenance, or repair activities performed on any EtO CEMS in a location and format suitable for inspection. A maintenance log may be used for this purpose. The following records should be maintained: Date, time, and description of any testing, adjustment, repair, replacement, or preventive maintenance action performed on any monitoring system and records of any corrective actions associated with a monitor outage period. Additionally, any adjustment that may significantly affect a system's ability to accurately measure emissions data must be recorded and a written explanation of the

procedures used to make the adjustment(s) shall be kept.

8.2 *Specific Requirements for EtO CEMS.* The following requirements are specific to EtO CEMS:

8.2.1 Keep a written record of the procedures used for each type of QA test required for each EtO CEMS. Explain how the results of each type of QA test are calculated and evaluated.

8.2.2 Explain how each component of the EtO CEMS will be adjusted to provide correct responses to calibration gases after routine maintenance, repairs, or corrective actions.

9. Data Reduction and Calculations

9.1 Design and operate the EtO CEMS to complete a minimum of one cycle of operation (sampling, analyzing, and data recording) for each successive 15-minute period.

9.2 Reduce the EtO concentration data to hourly averages in accordance with § 60.13(h)(2) of this chapter.

9.3 Convert each hourly average EtO concentration to an EtO mass emission rate (lb/hr) using an equation that has the general form of equation A–1 of this appendix:

$$E_{ho} = KC_hQ_h \qquad \text{(Eq. A-1)}$$

Where:

E_{ho} = EtO mass emission rate for the hour, lb/hr

K = Units conversion constant, 1.144E–10 lb/scf-ppbv,

Ch = Hourly average EtO concentration, ppbv,

Q_h = Stack gas volumetric flow rate for the hour, scfh.

(**Note:** Use unadjusted flow rate values; bias adjustment is not required.)

9.4 Use equation A–2 of this appendix to calculate the daily total EtO emissions. Report each daily total to the same precision as the most stringent standard that applies to any affected source exhausting to the emission stream (*e.g.,* if the emission stream includes contributions from an SCV and ARV subject to 99.99% and 99.9% emission reduction standards, respectively, report to four significant figures), expressed in scientific notation.

$$E_{day} = \sum_{h=1}^{24} (E_{ho} * 1\ hr) \qquad \text{Equation A-2}$$

Where:

E_{day} = Total daily EtO emissions, lb.

E_{ho} = Hourly EtO emission rate for unit or stack sampling hour ''h'' in the averaging period, from equation A–1 of this appendix, lb/hr.

9.5 Use equation A–3 of this appendix to calculate the 30-operating day rolling total EtO emissions. Report each 30-operating day rolling total to the same precision as the most stringent standard that applies to any affected source exhausting to the emission stream (*e.g.,* if the emission stream includes contributions from an SCV and ARV subject to 99.99% and 99.9% emission reduction standards, respectively, report to four significant figures), expressed in scientific notation.

$$E_{30day} = \sum_{i=1}^{30} E_{day,i} \qquad \text{Equation A-3}$$

Where:

E_{30day} = Total EtO emissions during the 30-operating day, lb.

$E_{day,i}$ = Total daily EtO emissions, in lbs, for each operating day *i* from equation A–2 of this appendix, lb.

$_i$ = Operating day index.

10. Recordkeeping Requirements

10.1 For each EtO CEMS installed at an affected source, and for any other monitoring system(s) needed to convert pollutant concentrations to units of the applicable emissions limit, the owner or operator must maintain a file of all measurements, data, reports, and other information required by this appendix in a form suitable for inspection, for 5 years from the date of each record, in accordance with § 63.367. The file shall contain the information in paragraphs 10.1.1 through 10.1.8 of this section.

10.1.1 *Monitoring Plan Records.* For each affected source or group of sources monitored at a common stack, the owner or operator shall prepare and maintain a monitoring plan for the EtO CEMS and any other monitoring system(s) (*i.e.,* flow rate, diluent gas, or moisture systems) needed to convert pollutant concentrations to units of the applicable emission standard. The monitoring plan shall contain essential information on the continuous monitoring systems and shall explain how the data derived from these systems ensure that all EtO emissions from the unit or stack are monitored and reported.

10.1.1.1 *Updates.* Whenever the owner or operator makes a replacement, modification, or change in a certified continuous EtO monitoring system that is used to provide data under this subpart (including a change in the automated data acquisition and handling system or the flue gas handling system) which affects information reported in the monitoring plan (*e.g.,* a change to a serial number for a component of a monitoring system), the owner or operator shall update the monitoring plan.

10.1.1.2 *Contents of the Monitoring Plan.* For EtO CEMS, the monitoring plan shall contain the applicable electronic and hard copy information in sections 10.1.1.2.1 and 10.1.1.2.2 of this appendix. For stack gas flow rate, diluent gas, and moisture monitoring systems, the monitoring plan shall include the electronic and hard copy information required for those systems under § 75.53(g) of this chapter. The electronic monitoring plan shall be evaluated using CEDRI.

10.1.1.2.1 *Electronic.* Record the unit or stack ID number(s); monitoring location(s); the EtO monitoring methodology used (*i.e.,* CEMS); EtO monitoring system information, including, but not limited to: unique system and component ID numbers; the make, model, and serial number of the monitoring equipment; the sample acquisition method; formulas used to calculate emissions; monitor span and range information (if applicable).

10.1.1.2.2 *Hard Copy.* Keep records of the following: schematics and/or blueprints showing the location of the monitoring system(s) and test ports; data flow diagrams; test protocols; monitor span and range calculations (if applicable); miscellaneous technical justifications.

10.1.2 *EtO Emissions Records.* For EtO CEMS, the owner or operator must record the following information for each unit or stack operating hour:

10.1.2.1 The date and hour;

10.1.2.2 Monitoring system and component identification codes, as provided in the electronic monitoring plan, for each hour in which the CEMS provides a quality-assured value of EtO concentration (as applicable);

10.1.2.3 The pollutant concentration, for each hour in which a quality-assured value is obtained. Record the data in parts per billion by volume (ppbv), with one leading non-zero digit and one decimal place, expressed in scientific notation. Use the following rounding convention: If the digit immediately following the first decimal place

is 5 or greater, round the first decimal place upward (increase it by one); if the digit immediately following the first decimal place is 4 or less, leave the first decimal place unchanged.

10.1.2.4 A special code, indicating whether or not a quality-assured EtO concentration value is obtained for the hour. This code may be entered manually when a temporary like-kind replacement EtO analyzer is used for reporting; and

10.1.2.5 Monitor data availability, as a percentage of unit or stack operating hours, calculated according to § 75.32 of this chapter.

10.1.3 *Stack Gas Volumetric Flow Rate Records.*

10.1.3.1 Hourly measurements of stack gas volumetric flow rate during unit operation are required to demonstrate compliance with EtO emission standards.

10.1.3.2 Use a flow rate monitor that meets the requirements of part 75 of this chapter to record the required data. You must keep hourly flow rate records, as specified in § 75.57(c)(2) of this chapter.

10.1.4 *EtO Emission Rate Records.* Record the following information for each affected unit or common stack:

10.1.4.1 The date and hour;

10.1.4.2 The hourly EtO emissions rate (lb/hr), for each hour in which valid values of EtO concentration and stack gas volumetric flow rate are obtained for the hour. Report each emission rate to the same precision as the most stringent standard that applies to any affected source exhausting to the emission stream (*e.g.,* if the emission stream includes contributions from an SCV and ARV subject to 99.99% and 99.9% emission reduction standards, respectively, report to four significant figures), expressed in scientific notation. Use the following rounding convention: If the digit immediately following the first decimal place is 5 or greater, round the first decimal place upward (increase it by one); if the digit immediately following the first decimal place is 4 or less, leave the first decimal place unchanged;

10.1.4.4 A code indicating that the EtO emission rate was not calculated for the hour, if valid data for EtO concentration and/or any of the other necessary parameters are not obtained for the hour. For the purposes of this appendix, the substitute data values required under part 75 of this chapter for stack gas flow rate are not considered to be valid data.

10.1.5 *Certification and Quality Assurance Test Records.* For the EtO CEMS used to provide data under this subpart at each affected unit (or group of units monitored at a common stack), record the following information for all required certification, recertification, diagnostic, and quality-assurance tests:

10.1.5.1 EtO CEMS.

10.1.5.1.1 For each required 7-day and daily calibration drift (CD) test or daily calibration error test (including daily calibration transfer standard tests) of the EtO CEMS, record the test date(s) and time(s), reference gas value(s), monitor response(s), and calculated calibration drift or calibration error value(s). If you use the dynamic spiking option for the mid-level calibration drift check under PS 19, you must also record the measured concentration of the native EtO in the flue gas before and after the spike and the spiked gas dilution factor.

10.1.5.1.2 or each required RATA of an EtO CEMS, record the beginning and ending date and time of each test run, the reference method(s) used, and the reference method and EtO CEMS run values. Keep records of stratification tests performed (if any), all of the raw field data, relevant process operating data, and all of the calculations used to determine the relative accuracy.

10.1.5.1.3 For each required measurement error (ME) test of an EtO monitor, record the date and time of each gas injection, the reference gas concentration (low, mid, or high) and the monitor response for each of the three injections at each of the three levels. Also record the average monitor response and the ME at each gas level and the related calculations.

10.1.5.1.4 For each required level of detection (LOD) test of an EtO monitor performed in a controlled environment, record the test date, the concentrations of the reference gas and interference gases, the results of the seven (or more) consecutive measurements of EtO, the standard deviation, and the LOD value. For each required LOD test performed in the field, record the test date, the three measurements of the native source EtO concentration, the results of the three independent standard addition (SA) measurements known as standard addition response (SAR), the effective spike addition gas concentration, the resulting standard addition detection level (SADL) value and all related calculations. For extractive CEMS performing the SA using dynamic spiking, you must record the spiked gas dilution factor.

10.1.5.1.5 For each required ME/level of detection response time test of an EtO monitor, record the test date, the native EtO concentration of the flue gas, the reference gas value, the stable reference gas readings, the upscale/downscale start and end times, and the results of the upscale and downscale stages of the test.

10.1.5.1.6 For each required interference test of an EtO monitor, record (or obtain from the analyzer manufacturer records of): The date of the test; the gas volume/rate, temperature, and pressure used to conduct the test; the EtO concentration of the reference gas used; the concentrations of the interference test gases; the baseline EtO responses for each interferent combination spiked; and the total percent interference as a function of span or EtO concentration.

10.1.5.1.7 For each quarterly relative accuracy audit (RAA) of an EtO monitor, record the beginning and ending date and time of each test run, the reference method used, the EtO concentrations measured by the reference method and CEMS for each test run, the average concentrations measured by the reference method and the CEMS, and the calculated relative accuracy. Keep records of the raw field data, relevant process operating data, and the calculations used to determine the relative accuracy.

10.1.5.1.8 For each quarterly cylinder gas audit (CGA) of an EtO monitor, record the date and time of each injection, and the reference gas concentration (zero, mid, or high) and the monitor response for each injection. Also record the average monitor response and the calculated ME at each gas level.

10.1.5.1.9 For each quarterly dynamic spiking audit (DSA) of an EtO monitor, record the date and time of the zero gas injection and each spike injection, the results of the zero gas injection, the gas concentrations (mid and high) and the dilution factors and the monitor response for each of the six upscale injections as well as the corresponding native EtO concentrations measured before and after each injection. Also record the average dynamic spiking error for each of the upscale gases, the calculated average DSA Accuracy at each upscale gas concentration, and all calculations leading to the DSA Accuracy.

10.1.5.2 *Additional Monitoring Systems.* For the stack gas flow rate monitoring systems described in section 3.2 of this appendix, you must keep records of all certification, recertification, diagnostic, and on-going quality-assurance tests of these systems, as specified in § 75.59(a) of this chapter.

11. Reporting Requirements

11.1 *General Reporting Provisions.* The owner or operator shall comply with the following requirements for reporting EtO emissions from each affected unit (or group of units monitored at a common stack):

11.1.1 Notifications, in accordance with paragraph 11.2 of this section;

11.1.2 Monitoring plan reporting, in accordance with paragraph 11.3 of this section;

11.1.3 Certification, recertification, and QA test submittals, in accordance with paragraph 11.4 of this section; and

11.1.4 Electronic quarterly report submittals, in accordance with paragraph 11.5 of this section.

11.2 *Notifications.* The owner or operator shall provide notifications for each affected unit (or group of units monitored at a common stack) in accordance with § 63.366.

11.3 *Monitoring Plan Reporting.* For each affected unit (or group of units monitored at a common stack) using EtO CEMS, the owner or operator shall make electronic and hard copy monitoring plan submittals as follows:

11.3.1 For a sterilization facility that begins reporting hourly EtO concentrations with a previously certified CEMS, submit the monitoring plan information in section 10.1.1.2 of this appendix prior to or concurrent with the first required quarterly emissions report. For a new sterilization facility, submit the information in section 10.1.1.2 of this appendix at least 21 days prior to the start of initial certification testing of the CEMS. Also submit the monitoring plan information in § 75.53(g) of this chapter pertaining to any required flow rate monitoring systems within the applicable timeframe specified in this section, if the required records are not already in place.

11.3.2 Update the monitoring plan when required, as provided in paragraph 10.1.1.1 of this appendix. An electronic monitoring plan information update must be submitted either

prior to or concurrent with the quarterly report for the calendar quarter in which the update is required.

11.3.3 All electronic monitoring plan submittals and updates shall be made to the Administrator using CEDRI. Hard copy portions of the monitoring plan shall be kept on record according to section 10.1 of this appendix.

11.4 *Certification, Recertification, and Quality-Assurance Test Reporting Requirements.* Use CEDRI to submit the results of all required certification, recertification, quality-assurance, and diagnostic tests of the monitoring systems required under this appendix electronically. Submit the test results concurrent with the quarterly electronic emissions report. However, for RATAs of the EtO monitor, if this is not possible, you have up to 60 days after the test completion date to submit the test results; in this case, you may claim provisional status for the emissions data affected by the test, starting from the date and hour in which the test was completed and continuing until the date and hour in which the test results are submitted. If the test is successful, the status of the data in that time period changes from provisional to quality-assured, and no further action is required. However, if the test is unsuccessful, the provisional data must be invalidated and resubmission of the affected emission report(s) is required.

11.4.1 For each daily CD (or calibration error) assessment (including daily calibration transfer standard tests), and for each seven-day calibration drift (CD) test of an EtO monitor, report:

11.4.1.1 Facility ID information;

11.4.1.2 The monitoring component ID;

11.4.1.3 The instrument span and span scale;

11.4.1.4 For each gas injection, the date and time, the calibration gas level (zero or high-level), the reference gas value (ppbv), and the monitor response (ppbv);

11.4.1.5 A flag to indicate whether dynamic spiking was used for the high-level value;

11.4.1.6 Calibration drift (percent of span or reference gas, as applicable);

11.4.1.7 When using the dynamic spiking option, the measured concentration of native EtO before and after each mid-level spike and the spiked gas dilution factor; and

11.4.1.8 Reason for test.

11.4.2 For each RATA of an EtO CEMS, report:

11.4.2.1 Facility ID information;

11.4.2.2 Monitoring system ID number;

11.4.2.3 Type of test (*i.e.,* initial or annual RATA);

11.4.2.4 Reason for test;

11.4.2.5 The reference method used;

11.4.2.6 Starting and ending date and time for each test run;

11.4.2.7 Units of measure;

11.4.2.8 The measured reference method and CEMS values for each test run, on a consistent moisture basis, in appropriate units of measure;

11.4.2.9 Flags to indicate which test runs were used in the calculations;

11.4.2.10 Arithmetic mean of the CEMS values, of the reference method values, and of their differences;

11.4.2.11 Standard deviation, using equation 7 in section 12.6 of PS 19 in appendix B to part 60 of this chapter;

11.4.2.12 Confidence coefficient, using equation 8 in section 12.6 of PS 19 in appendix B to part 60 of this chapter;

11.4.2.13 t-value; and

11.4.2.14 Relative accuracy calculated using equation 11 in section 12.6 of PS 19 in appendix B to part 60 of this chapter.

11.4.3 For each measurement error (ME) test of an EtO monitor, report:

11.4.3.1 Facility ID information;

11.4.3.2 Monitoring component ID;

11.4.3.3 Instrument span and span scale;

11.4.3.4 For each gas injection, the date and time, the calibration gas level (zero, low, mid, or high), the reference gas value in ppbv and the monitor response.

11.4.3.5 For extractive CEMS, the mean reference value and mean of measured values at each reference gas level (ppbv).

11.4.3.6 ME at each reference gas level; and

11.4.3.7 Reason for test.

11.4.4 For each interference test of an EtO monitoring system, report:

11.4.4.1 Facility ID information;

11.4.4.2 Date of test;

11.4.4.3 Monitoring system ID;

11.4.4.4 Results of the test (pass or fail);

11.4.4.5 Reason for test; and

11.4.4.6 A flag to indicate whether the test was performed: On this particular monitoring system; on one of multiple systems of the same type; or by the manufacturer on a system with components of the same make and model(s) as this system.

11.4.5 For each LOD test of an EtO monitor, report:

11.4.5.1 Facility ID information;

11.4.5.2 Date of test;

11.4.5.3 Reason for test;

11.4.5.4 Monitoring system ID;

11.4.5.5 A code to indicate whether the test was done in a controlled environment or in the field;

11.4.5.6 EtO reference gas concentration;

11.4.5.7 EtO responses with interference gas (seven repetitions);

11.4.5.8 Standard deviation of EtO responses;

11.4.5.9 Effective spike addition gas concentrations;

11.4.5.10 EtO concentration measured without spike;

11.4.5.11 EtO concentration measured with spike;

11.4.5.12 Dilution factor for spike;

11.4.5.13 The controlled environment LOD value (ppbv or ppbv-meters);

11.4.5.14 The field determined standard addition detection level (SADL in ppbv or ppbv-meters); and

11.4.5.15 Result of LOD/SADL test (pass/fail).

11.4.6 For each ME or LOD response time test of an EtO monitor, report:

11.4.6.1 Facility ID information;

11.4.6.2 Date of test;

11.4.6.3 Monitoring component ID;

11.4.6.4 The higher of the upscale or downscale tests, in minutes; and

11.4.6.5 Reason for test.

11.4.7 For each quarterly RAA of an EtO monitor, report:

11.4.7.1 Facility ID information;

11.4.7.2 Monitoring system ID;

11.4.7.3 Begin and end time of each test run;

11.4.7.4 The reference method used;

11.4.7.5 The reference method and CEMS values for each test run, including the units of measure;

11.4.7.6 The mean reference method and CEMS values for the three test runs;

11.4.7.7 The calculated relative accuracy, percent; and

11.4.7.8 Reason for test.

11.4.8 For each quarterly cylinder gas audit of an EtO monitor, report:

11.4.8.1 Facility ID information;

11.4.8.2 Monitoring component ID;

11.4.8.3 Instrument span and span scale;

11.4.8.4 For each gas injection, the date and time, the reference gas level (zero, mid, or high), the reference gas value in ppbv, and the monitor response.

11.4.8.5 For extractive CEMS, the mean reference gas value and mean monitor response at each reference gas level (ppbv).

11.4.8.6 ME at each reference gas level; and

11.4.8.7 Reason for test.

11.4.9 For each quarterly DSA of an EtO monitor, report:

11.4.9.1 Facility ID information;

11.4.9.2 Monitoring component ID;

11.4.9.3 Instrument span and span scale;

11.4.9.4 For the zero gas injection, the date and time, and the monitor response (Note: The zero gas injection from a calibration drift check performed on the same day as the upscale spikes may be used for this purpose.);

11.4.9.5 Zero spike error;

11.4.9.6 For the upscale gas spiking, the date and time of each spike, the reference gas level (mid- or high-), the reference gas value (ppbv), the dilution factor, the native EtO concentrations before and after each spike, and the monitor response for each gas spike;

11.4.9.7 Upscale spike error;

11.4.9.8 DSA at the zero level and at each upscale gas level; and

11.4.9.9 Reason for test.

11.4.10 *Reporting Requirements for Diluent Gas, Flow Rate, and Moisture Monitoring Systems.* For the certification, recertification, diagnostic, and QA tests of stack gas flow rate, moisture, and diluent gas monitoring systems that are certified and quality-assured according to part 75 of this chapter, report the information in section 10.1.8.2 of this appendix.

11.5 *Quarterly Reports.*

11.5.1 The owner or operator of any affected unit shall use CEDRI to submit electronic quarterly reports to the Administrator in an XML format specified by the Administrator, for each affected unit (or group of units monitored at a common stack). If the certified EtO CEMS is used for the initial compliance demonstration, EtO emissions reporting shall begin with the first operating hour of the 30-operating day compliance demonstration period. Otherwise, EtO emissions reporting shall begin with the first operating hour after successfully completing all required certification tests of the CEMS.

11.5.2 The electronic reports must be submitted within 30 days following the end

of each calendar quarter, except for units that have been placed in long-term cold storage.

11.5.3 Each electronic quarterly report shall include the following information:

11.5.3.1 The date of report generation;

11.5.3.2 Facility identification information;

11.5.3.3 The information in sections 10.1.2 through 10.1.4 of this appendix, as applicable to the type(s) of monitoring system(s) used to measure the pollutant concentrations and other necessary parameters.

11.5.3.4 The results of all daily calibrations (including calibration transfer standard tests) of the EtO monitor as described in section 10.1.8.1.1 of this appendix; and

11.5.3.5 If applicable, the results of all daily flow monitor interference checks, in accordance with section 10.1.8.2 of this appendix.

11.5.4 *Compliance Certification.* Based on reasonable inquiry of those persons with primary responsibility for ensuring that all EtO emissions from the affected unit(s) have been correctly and fully monitored, the owner or operator shall submit a compliance certification in support of each electronic quarterly emissions monitoring report. The compliance certification shall include a statement by a responsible official with that official's name, title, and signature, certifying that, to the best of his or her knowledge, the report is true, accurate, and complete.

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Part III

Department of Energy

10 CFR Parts 429 and 430

Energy Conservation Program: Test Procedure for Central Air Conditioners and Heat Pumps; Proposed Rule

DEPARTMENT OF ENERGY

10 CFR Parts 429 and 430

[EERE–2022–BT–TP–0028]

RIN 1904–AF49

Energy Conservation Program: Test Procedure for Central Air Conditioners and Heat Pumps

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

ACTION: Notice of proposed rulemaking and announcement of public meeting.

SUMMARY: The U.S. Department of Energy (''DOE'') proposes to amend the Federal test procedure for central air conditioners and heat pumps (''CAC/HPs'') to incorporate by reference the latest versions of the applicable industry standards. Specifically, DOE proposes: to amend the current test procedure for CAC/HPs (''appendix M1'') for measuring the current cooling and heating metrics—seasonal energy efficiency ratio 2 (''SEER2'') and heating seasonal performance factor 2 (''HSPF2''), respectively; and to establish a new test procedure (''appendix M2'') for CAC/HPs that would adopt two new metrics—seasonal cooling and off-mode rating efficiency (''SCORE'') and seasonal heating and off-mode rating efficiency (''SHORE''). Testing to the SCORE and SHORE metrics would not be required until such time as compliance is required with any amended energy conservation standard based on the new metrics. Additionally, DOE proposes to amend certain provisions of DOE's regulations related to representations and enforcement for CAC/HPs. DOE welcomes written comments from the public on any subject within the scope of this document (including relevant topics not raised in this proposal), as well as the submission of data and other relevant information.

DATES:

Comments: DOE will accept comments, data, and information regarding this proposal no later than June 4, 2024. *See* section V, ''Public Participation,'' for details.

Meeting: DOE will hold a public meeting via webinar on Thursday, April 25, 2024, from 1:00 p.m. to 4:00 p.m. *See* section V, ''Public Participation,'' for webinar registration information, participant instructions, and information about the capabilities available to webinar participants.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *www.regulations.gov* under docket number EERE–2022–BT–TP–0028. Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2022–BT–TP–0028, by any of the following methods:

(1) *Email: CACandHeatPump2022TP0028@ee.doe.gov.* Include the docket number EERE–2022–BT–TP–0028 in the subject line of the message.

(2) *Postal Mail:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–1445. If possible, please submit all items on a compact disc (''CD''), in which case it is not necessary to include printed copies.

(3) *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW, 6th Floor, Washington, DC 20024. Telephone: (202) 287–1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimiles (''faxes'') will be accepted. For detailed instructions on submitting comments and additional information on this process, *see* section V of this document.

Docket: The docket for this activity, which includes **Federal Register** notices, public meeting attendee lists and transcripts (if a public meeting is held), comments, and other supporting documents/materials, is available for review at *www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

The docket web page can be found at *www.regulations.gov/docket/EERE-2022-BT-TP-0028.* The docket web page contains instructions on how to access all documents, including public comments, in the docket. *See* section V for information on how to submit comments through *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

Mr. Lucas Adin, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–2J, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–5904. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Mr. Pete Cochran, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–9496. Email: *peter.cochran@hq.doe.gov.*

For further information on how to submit a comment, review other public comments and the docket, or participate in a public meeting (if one is held), contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: DOE proposes to maintain previously approved incorporations by reference and incorporate by reference the following industry standards into 10 CFR parts 429 and 430:

AHRI 210/240–202X, *202X Standard for Performance Rating of Unitary Air-Conditioning & Air-Source Heat Pump Equipment* (''AHRI 210/240–202X Draft''). AHRI 210/240–202X Draft is in draft form and this draft was announced for public review on November 16, 2023.[1] DOE references this version for the purposes of drafting this Notice of Proposed Rulemaking (''NOPR''). If this industry test standard is formally adopted, DOE intends to incorporate by reference the final published version of AHRI 210/240, not the current draft version, in DOE's subsequent test procedure final rule, unless there are substantive changes between the draft and final versions, in which case DOE may adopt the substance of the AHRI 210/240–202X Draft or provide additional opportunity for comment on the changes to the industry consensus standard.

AHRI 1600–202X, *202X Standard for Performance Rating of Unitary Air-Conditioning & Air-Source Heat Pump Equipment* (''AHRI 1600–202X Draft''). AHRI 1600–202X Draft is in draft form and this draft was announced for public review on November 16, 2023.[2] DOE references this version for the purposes of drafting this NOPR. If this industry test standard is formally adopted, DOE intends to incorporate by reference the final published version of AHRI 1600, not the current draft version, in DOE's subsequent test procedure final rule, unless there are substantive changes between the draft and published versions, in which case DOE may adopt the substance of the AHRI 1600–202X

[1] Public review of AHRI 210/240–202X Draft was announced in the November 16, 2023 AHRI Update here: *http://newsmanager.commpartners.com/ahri/issues/2023-11-16-email.html.*

[2] Public review of AHRI 1600–202X Draft was also announced in the November 16, 2023 AHRI Update here: *http://newsmanager.commpartners.com/ahri/issues/2023-11-16-email.html.*

Draft or provide additional opportunity for comment on the changes to the industry consensus standard.

Copies of the AHRI 210/240–202X Draft and AHRI 1600–202X Draft are available in the docket for this proposed rulemaking for review.

ANSI/ASHRAE Standard 16–2016, *Method of Testing for Rating Room Air Conditioners, Packaged Terminal Air Conditioners, and Packaged Terminal Heat Pumps for Cooling and Heating Capacity,* ANSI approved November 1, 2016, (''ANSI/ASHRAE 16–2016'').

ANSI/ASHRAE Standard 37–2009, *Methods of Testing for Rating Electrically Driven Unitary Air-Conditioning and Heat Pump Equipment,* ANSI approved June 25, 2009, (''ANSI/ASHRAE 37–2009'').

ANSI/ASHRAE 116–2010, *Methods of Testing for Rating Seasonal Efficiency of Unitary Air Conditioners and Heat Pumps,* ANSI approved February 24, 2010, (''ASHRAE 116–2010'').

Copies of ANSI/ASHRAE 16–2016, ANSI/ASHRAE 37–2009, and ASHRAE 116–2010 can be purchased from the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (''ASHRAE'') website at *www.ashrae.org/resources--publications.*

See section IV.M of this document for further discussion of these standards.

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I. Authority and Background

Central air conditioners (''CACs'') and central air conditioning heat pumps (''HPs'') (collectively, ''CAC/HPs'') are included in the list of ''covered products'' for which DOE is authorized to establish and amend energy conservation standards and test procedures. (42 U.S.C. 6292(a)(3)) DOE's test procedures for CAC/HPs are currently prescribed at 10 CFR part 430, subpart B, appendix M1 (''appendix M1''). The following sections discuss DOE's authority to establish and amend test procedures for CAC/HPs and relevant background information regarding DOE's consideration of test procedures for this product.

A. Authority

The Energy Policy and Conservation Act, Pub. L. 94–163, as amended (''EPCA''),[3] authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, Part B of EPCA [4] established the Energy Conservation Program for Consumer Products Other Than Automobiles, which sets forth a variety of provisions designed to improve energy efficiency. These products include CAC/HPs, the subject of this document. (42 U.S.C. 6292(a)(3))

The energy conservation program under EPCA consists essentially of four parts: (1) testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement

[3] All references to EPCA in this document refer to the statute as amended through the Energy Act of 2020, Public Law 116–260 (Dec. 27, 2020), which reflect the last statutory amendments that impact Parts A and A–1 of EPCA.

[4] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

procedures. Relevant provisions of EPCA specifically include definitions (42 U.S.C. 6291), test procedures (42 U.S.C. 6293), labeling provisions (42 U.S.C. 6294), energy conservation standards (42 U.S.C. 6295), and the authority to require information and reports from manufacturers (42 U.S.C. 6296).

The Federal testing requirements consist of test procedures that manufacturers of covered products must use as the basis for: (1) certifying to DOE that their products comply with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6295(s)), and (2) making other representations about the efficiency of those consumer products (42 U.S.C. 6293(c)). Similarly, DOE must use these test procedures to determine whether the products comply with relevant standards promulgated under EPCA. (42 U.S.C. 6295(s))

Federal energy efficiency requirements for covered products established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6297) DOE may, however, grant waivers of Federal preemption for particular State laws or regulations, in accordance with the procedures and other provisions of EPCA. (42 U.S.C. 6297(d))

Under 42 U.S.C. 6293, EPCA sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered products. EPCA requires that any test procedures prescribed or amended under this section be reasonably designed to produce test results which measure energy efficiency, energy use, or estimated annual operating cost of a covered product during a representative average use cycle or period of use and not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3))

EPCA also requires that, at least once every 7 years, DOE evaluate test procedures for each type of covered product, including CAC/HPs, to determine whether amended test procedures would more accurately or fully comply with the requirements for the test procedures to not be unduly burdensome to conduct and be reasonably designed to produce test results that reflect energy efficiency, energy use, and estimated operating costs during a representative average use cycle or period of use. (42 U.S.C. 6293(b)(1)(A))

If the Secretary determines, on her own behalf or in response to a petition by any interested person, that a test procedure should be prescribed or amended, the Secretary shall promptly publish in the **Federal Register** proposed test procedures and afford interested persons an opportunity to present oral and written data, views, and arguments with respect to such procedures. The comment period on a proposed rule to amend a test procedure shall be at least 60 days and may not exceed 270 days. In prescribing or amending a test procedure, the Secretary shall take into account such information as the Secretary determines relevant to such procedure, including technological developments relating to energy use or energy efficiency of the type (or class) of covered products involved. (42 U.S.C. 6293(b)(2)). If DOE determines that test procedure revisions are not appropriate, DOE must publish its determination not to amend the test procedures. (42 U.S.C. 6293(b)(1)(A)(ii))

In addition, EPCA requires that DOE amend its test procedures for all covered products to integrate measures of standby mode and off mode energy consumption. (42 U.S.C. 6295(gg)(2)(A)) Standby mode and off mode energy consumption must be incorporated into the overall energy efficiency, energy consumption, or other energy descriptor for each covered product unless the current test procedures already account for and incorporate standby and off mode energy consumption or such integration is technically infeasible. If an integrated test procedure is technically infeasible, DOE must prescribe a separate standby mode and off mode energy use test procedure for the covered product, if technically feasible. (42 U.S.C. 6295(gg)(2)(A)(ii)) Any such amendment must consider the most current versions of the International Electrotechnical Commission (''IEC'') Standard 62301 [5] and IEC Standard 62087 [6] as applicable. (42 U.S.C. 6295(gg)(2)(A))

DOE is publishing this NOPR in satisfaction of the 7-year review requirement specified in EPCA. (42 U.S.C. 6293(b)(1)(A))

B. Background

On January 5, 2017, DOE published a final rule regarding the Federal test procedures for CAC/HPs. 82 FR 1426 (''January 2017 Final Rule''). The January 2017 Final Rule amended the current test procedure at that time, 10 CFR part 430, subpart B, appendix M (''appendix M'') and established appendix M1, use of which was required beginning January 1, 2023, for any representations, including compliance certifications, made with respect to the energy use or efficiency of CAC/HPs. Appendix M provides for the measurement of the cooling and heating performance of CAC/HPs using the seasonal energy efficiency ratio (''SEER'') metric and heating seasonal performance factor (''HSPF'') metric, respectively. Appendix M1 specifies a revised SEER metric (*i.e.,* ''SEER2'') and a revised HSPF metric (*i.e.,* ''HSPF2'').

On October 25, 2022, DOE published a final rule to address limited-scope amendments to the existing test procedures for CAC/HPs in appendix M1. 87 FR 64550 (''October 2022 Final Rule''). The October 2022 Final Rule provided changes to improve the functionality of appendix M1 to address the issues identified in test procedure waivers, improve representativeness, and correct typographical issues raised by commenters. *Id.* at 87 FR 64551. In the October 2022 Final Rule, DOE noted that several commenters indicated the need for test procedure amendments beyond the scope of the rulemaking. *Id.* at 87 FR 64554–64555. DOE received comments recommending consideration of load-based testing methods, controls validation (particularly for variable speed systems), amended metrics, amended definitions, and expansion of test methods to capture low-temperature heating performance for heat pumps. *Id.* In its response to these comments, DOE noted that it had initiated that rulemaking not as a comprehensive revision that would satisfy the 7-year lookback requirements (*see* 42 U.S.C. 6293(b)(1)(A)), but to address a limited set of known issues, including those that have been raised through the test procedure waiver process. 87 FR 64554. DOE, however, also acknowledged that a future rulemaking may more comprehensively address the issues raised by the commenters. *Id.*

On January 24, 2023, DOE published in the **Federal Register** a request for information (''RFI'') regarding the need for amendments to the test procedures for CAC/HPs, including the need for amendments to address the issues raised by commenters in the previous rulemaking, in satisfaction of the 7-year review requirements specified in EPCA. 88 FR 4091 (''January 2023 RFI''). In the January 2023 RFI, DOE requested comments, information, and data about a number of issues, and considered these issues in two separate categories: (1) the consideration of load-based testing methodologies under development by various organizations and whether certain aspects of these methodologies might be adopted into

[5] IEC 62301, *Household electrical appliances—Measurement of standby power* (Edition 2.0, 2011–01).

[6] IEC 62087, *Audio, video and related equipment—Methods of measurement for power consumption* (Edition 1.0, Parts 1–6: 2015, Part 7: 2018).

the DOE test procedure; and (2) issues with the current appendix M1 test procedure that may or may not still be relevant if or when load-based concepts are adopted in the DOE test procedure. *Id.* at 88 FR 4092–4093.

DOE received comments in response to the January 2023 RFI from the interested parties listed in Table I.1.

TABLE I.1—LIST OF COMMENTERS WITH WRITTEN SUBMISSIONS IN RESPONSE TO THE JANUARY 2023 RFI

Commenter(s)	Reference in this NOPR	Comment No. in the docket	Commenter type
Air-Conditioning, Heating, and Refrigeration Institute	AHRI	14	Trade Association.
Appliance Standards Awareness Project, American Council for an Energy-Efficient Economy, Consumer Federation of America, and National Consumer Law Center.	Joint Advocates	8	Efficiency Organizations and Consumer Advocacy Organizations.
British Columbian Hydro and Power Authority	BC Hydro	15	Utility.
Pacific Gas and Electric Company, San Diego Gas and Electric, and Southern California Edison; collectively, the California Investor-Owned Utilities.	CA IOUs	10	Utilities.
Carrier Global Corporation	Carrier	5	Manufacturer.
CoilPod LLC	CoilPod	4	Service Provider.
Daikin Comfort Technologies North America Inc	Daikin	16	Manufacturer.
Lennox International Inc	Lennox	6	Manufacturer.
National Comfort Products	NCP	7	Manufacturer.
Northwest Energy Efficiency Alliance	NEEA	13	Efficiency Organization.
New York State Energy Research and Development Authority	NYSERDA	9	State Agency.
Rheem Manufacturing Company	Rheem	12	Manufacturer.
Samsung HVAC	Samsung	11	Manufacturer.

A parenthetical reference at the end of a comment quotation or paraphrase provides the location of the item in the public record.[7]

In response to the January 2023 RFI, DOE received multiple comments regarding the energy conservation standards for CAC/HPs. Comments regarding energy conservation standards are outside the scope of consideration for this test procedure rulemaking and are not addressed in this NOPR. Topics related to energy conservation standards for CAC/HPs would be addressed in a separate rulemaking process.

II. Synopsis of the Notice of Proposed Rulemaking

In this NOPR, DOE proposes to update its test procedures for CAC/HPs by: (1) updating the reference in the Federal test procedure at appendix M1 to the most recent draft version of the AHRI Standard 210/240 industry test procedure, AHRI 210/240–202X Draft, for measuring SEER2 and HSPF2; and (2) establishing a new test procedure at 10 CFR part 430, subpart B, appendix M2 (''appendix M2'') that references the draft new industry test procedure, AHRI 1600–202X Draft, for measuring new efficiency metrics, seasonal cooling and off-mode rating efficiency (''SCORE''), and seasonal heating and off-mode rating efficiency (''SHORE'').

If AHRI 210/240–202X Draft and AHRI 1600–202X Draft are finalized and formally adopted, DOE intends to incorporate by reference the final published version of AHRI 210/240 and AHRI 1600 in DOE's subsequent test procedure final rule.

To implement the proposed changes, DOE proposes: (1) to amend appendix M1 to incorporate by reference AHRI 210/240–202X Draft for CAC/HPs, while maintaining the current efficiency metrics; and (2) to add a new appendix M2 to subpart F of 10 CFR part 430 to incorporate by reference AHRI 1600–202X Draft, which introduces new efficiency metrics, SCORE and SHORE. DOE would list appendix M2 as the applicable test method for CAC/HPs for any standards denominated in terms of SCORE and SHORE. Use of appendix M2 would not be required until such time as compliance is required with any amended energy conservation standard based on the new metrics, should DOE adopt such standards. After the date on which compliance with appendix M2 would be required, appendix M1 would no longer be required as part of the Federal test procedure. DOE is also proposing to amend certain provisions within DOE's regulations for representation and enforcement consistent with the proposed test procedure amendments.

Table II.1 summarizes the current DOE test procedure for CAC/HPs, DOE's proposed changes to that test procedure, and the reason for each proposed change.

TABLE II.1—SUMMARY OF CHANGES IN PROPOSED APPENDIX M1 AND PROPOSED APPENDIX M2 TEST PROCEDURES RELATIVE TO CURRENT TEST PROCEDURE

Current DOE test procedure	Proposed appendix M1 test procedure	Proposed appendix M2 test procedure	Attribution
Incorporates by reference AHRI 210/240–2008.	Incorporates by reference AHRI 210/240–202X Draft.	Incorporates by reference AHRI 1600–202X Draft.	Updates to the applicable industry test procedures.
Includes provisions for determining SEER2, HSPF2, EER2, and $P_{W,OFF}$.	Maintains provisions for determining SEER2, HPSF2, EER2, and $P_{W,OFF}$.	Includes provisions for determining SCORE and SHORE and maintains provisions for determining EER2.	Updates to the applicable industry test procedures.

[7] The parenthetical reference provides a reference for information located in the docket of DOE's rulemaking to develop test procedures for CAC/HPs. (Docket No. EERE–2022–BT–TP–0028, which is maintained at *www.regulations.gov*). The references are arranged as follows: (commenter name, comment docket ID number, page of that document).

TABLE II.1—SUMMARY OF CHANGES IN PROPOSED APPENDIX M1 AND PROPOSED APPENDIX M2 TEST PROCEDURES RELATIVE TO CURRENT TEST PROCEDURE—Continued

Current DOE test procedure	Proposed appendix M1 test procedure	Proposed appendix M2 test procedure	Attribution
Includes certain CAC/HP provisions regarding determination of represented values in 10 CFR 429.16.	Includes provisions to remove the alternative efficiency determination method (''AEDM'') exception for split-systems in 10 CFR 429.16.	Includes provisions to remove the AEDM exception for split-systems, to extend the AEDM tolerance requirement to SCORE and SHORE, and to no longer require representations of the $P_{W,OFF}$ metric in 10 CFR 429.16.	Improve representativeness of test procedure.
Does not include certain CAC/HP-specific enforcement provisions in 10 CFR 429.134(k).	Includes CAC/HP-specific enforcement provisions regarding verification of cut-out and cut-in temperatures and a controls verification procedure.	Includes CAC/HP-specific enforcement provisions regarding verification of cut-out and cut-in temperatures and a controls verification procedure.	Clarify how DOE will conduct enforcement testing.

DOE has tentatively determined that the proposed amendments to the CAC/HP test procedures in appendix M1 and the proposed appendix M2 would not be unduly burdensome. Furthermore, DOE has tentatively determined that the proposed amendments to appendix M1, if made final, would not alter the measured efficiency of CAC/HPs or require retesting or recertification solely as a result of DOE's adoption of the proposed amendments to the test procedure. Additionally, DOE has tentatively determined that the proposed amendments to appendix M1, if made final, would not increase the cost of testing. If finalized, representations of energy use or energy efficiency would be required to be based on testing in accordance with the amended test procedure in appendix M1 beginning 180 days after the date of publication of the test procedure final rule in the **Federal Register**.

DOE has tentatively determined, however, that the newly proposed test procedure at appendix M2 would, if adopted, alter the measured efficiency of CAC/HPs, in part because the amended test procedure would adopt different energy efficiency metrics than in the current test procedure. Additionally, DOE has tentatively determined that the proposed amendments to appendix M2, if made final, would not increase the cost of testing. Tentative cost estimates are discussed in section III.L of this document. As discussed, use of appendix M2 would not be required until the compliance date of amended energy conservation standards denominated in terms of SCORE and SHORE, should DOE adopt such standards.

The proposed amendments to representation requirements in 10 CFR 429.43 would not be required until 180 days after publication in the **Federal Register** of a test procedure final rule.

Discussion of DOE's proposed actions are addressed in further detail in section III of this NOPR.

III. Discussion

In the following sections, DOE proposes certain amendments to its test procedures for CAC/HPs. For each proposed amendment, DOE provides relevant background information, explains why the proposed amendment merits consideration, discusses relevant public comments, and proposes a potential approach.

A. Scope of Applicability

This rulemaking applies to CAC/HPs. DOE defines the term *Central air conditioner or central air conditioner heat pump* to mean a product, other than a packaged terminal air conditioner or packaged terminal heat pump, single-phase single-package vertical air conditioner with cooling capacity less than 65,000 British thermal units (''Btu'') per hour (''Btu/h''), single-phase single-package vertical heat pump with cooling capacity less than 65,000 Btu/h, computer room air conditioner, or unitary dedicated outdoor air system as these equipment categories are defined at 10 CFR 431.92, which is powered by single phase electric current, air cooled, rated below 65,000 Btu/h, not contained within the same cabinet as a furnace, the rated capacity of which is above 225,000 Btu/h, and is a heat pump or a cooling unit only. A central air conditioner or central air conditioning heat pump may consist of: A single-package unit; an outdoor unit and one or more indoor units; an indoor unit only; or an outdoor unit with no match. In the case of an indoor unit only or an outdoor unit with no match, the unit *must* be tested and rated as a system (combination of both an indoor and an outdoor unit). 10 CFR 430.2.

Appendix M1 applies to the following CACs/HPs:

(a) Split-system air conditioners, including single-split, multi-head mini-split, multi-split (including VRF), and multi-circuit systems;

(b) Split-system heat pumps, including single-split, multi-head mini-split, multi-split (including VRF), and multi-circuit systems;

(c) Single-package air conditioners;

(d) Single-package heat pumps;

(e) Small-duct, high-velocity systems (including VRF);

(f) Space-constrained products—air conditioners; and

(g) Space-constrained products—heat pumps.

See section 1.1 of appendix M1.

DOE is not proposing to change the scope of CACs/HPs covered by the test procedure in appendix M1 or the proposed appendix M2.

B. Definitions

CAC/HPs are defined in 10 CFR 430.2, as described in the previous section. This definition was last amended in the October 2022 Final Rule. DOE revised the central air conditioner or central air conditioning heat pump definition so that it explicitly excluded certain equipment categories that met the CAC/HP definition based on their characteristics but are exclusively distributed in commerce for commercial and industrial applications. 87 FR 64550, 64573. DOE noted in the October 2022 Final Rule that there are certain types of equipment that meet the CAC/HP definition but are exclusively distributed in commerce for commercial and industrial applications, and that EPCA did not intend to regulate as consumer products. *Id.*

As laid out in section 1.1 of appendix M1, the test procedure applies to CAC/

HPs, including the following categories, which are defined either in 10 CFR 430.2 or in section 1.2 of appendix M1:

(a) Split-system air conditioners, including single-split, multi-head mini-split, multi-split (including variable refrigerant flow (''VRF'')), and multi-circuit systems;

(b) Split-system heat pumps, including single-split, multi-head mini-split, multi- split (including VRF), and multi-circuit systems;

(c) Single-package air conditioners;

(d) Single-package heat pumps;

(e) Small-duct, high-velocity systems (including VRF);

(f) Space-constrained products—air conditioners; and

(g) Space-constrained products—heat pumps.

In the January 2023 RFI, DOE sought comment on whether the definition of CAC/HP needs revision, and whether the scope of the appendices M and M1 needs to be limited, expanded, clarified, or revised in any way.[8] 88 FR 4091, 4093.

In its response, Rheem requested a revision to the definition and scope of CAC/HPs covered by appendix M1 to add a new product class of ''space-constrained vertical package'' product. (Rheem, No. 12 at pp. 1–2) Rheem proposed that this new product class would meet all definitions of the current ''space-constrained'' product class but also consist of the following three additions: (1) is factory-assembled as a single package that has major components that are arranged vertically; (2) is intended for interior mounting on adjacent, interior to, or through an outside wall; (3) and is non-weatherized. (*Id.*) Rheem suggested the product class delineation should be used to establish a reasonable minimum test external static pressure (''ESP'') of 0.15 inches of water column (''in. wc.''), which Rheem claimed will result in more congruity between tested and actual unit operation for the consumer for these types of units. *Id.*

Rheem asserted that DOE's current space-constrained product class is too general, and as a result puts unreasonable testing burden on ''space-constrained vertical package'' units. (*Id.*) Specifically, Rheem commented that the minimum ESP of 0.3 in. wc. required by appendix M1 for space-constrained products[9] is not representative of installations of these units. Rheem explained that ''space-constrained vertical package'' products are typically entirely installed inside a closet with a short supply duct of 5–15 feet, without a return duct, and usually are found within small multifamily or lodging applications (such as assisted living and low-income housing). (*Id.*) Additionally, Rheem noted that one of its brands, Friedrich, has multiple products in which operation at an ESP greater than 0.3 in. wc. is prohibited per the installation and operation instructions. (*Id.*) Rheem commented that designing and testing the equipment to meet the minimum 0.3 in. wc. requirement of the current space-constrained category will lead to size and cost changes that will serve no benefit to the consumer and would make replacement units cost or size prohibitive. (*Id.*)

DOE notes that Rheem's comment lacked sufficient information, such as product literature and test data, that would indicate that the current test procedure ESP requirement for ''space-constrained'' products is unsuitable for the products Rheem described in its comment, puts undue burden on manufacturers for testing, and is not representative of current installations of these units in the field. DOE is not aware of any space-constrained products that are not able to be tested according to the existing test procedure requirements. Given the limited information describing the products that are the subject of Rheem's comment, DOE is not proposing to amend the definition of space-constrained vertical package units within the scope of CAC/HPs.

Regarding the scope and definition of CAC/HPs, AHRI, Carrier, and Lennox all submitted comments relating to a definition for heat pumps optimized for performance in cold climates. (AHRI, No. 14 at p. 7; Carrier, No. 5 at p. 2; Lennox, No. 6 at p. 3) Comments regarding heat pumps optimized for low-temperature heating performance are discussed in section III.F.2 of this NOPR. AHRI also submitted a comment regarding systems that use a heat pump and a furnace in combination as a source for heating (*i.e.,* ''dual-fuel'' heat pumps). (AHRI, No. 14 at p. 7) Comments regarding such systems are discussed in section III.F.6 of this NOPR.

Notably, both Carrier and Lennox commented that they find the current scope of CAC/HPs covered by appendix M1 to be appropriate. (Carrier, No. 5 at p. 2; Lennox, No. 6 at p. 3) Lennox also stated that it finds the general definition of central air conditioner or central air conditioning heat pump to be adequate. (Lennox, No. 6 at p. 3)

Except as noted, DOE is not proposing any further amendments to the definition of central air conditioner or to the scope of CAC/HPs covered by appendix M1 or the newly proposed appendix M2.

C. Updates to Industry Standards

DOE's current test procedures for CAC/HPs are codified at appendix M1 and incorporate by reference various industry standards. The regulatory text at appendix M1 has generally been closely aligned with the relevant industry standard for CAC/HPs, AHRI Standard 210/240—however, several rulemakings have changed the regulatory portions of appendix M1 over time with amendments and additions, not all of which have been mirrored in the AHRI 210/240 standards.

Appendix M1 currently references ANSI/AHRI 210/240–2008 with Addenda 1 and 2 (''AHRI 210/240–2008'' [10]): 2008 Standard for Performance Rating of Unitary Air Conditioning & Air-Source Heat Pump Equipment. However, the latest AHRI Standard 210/240 is AHRI 210/240–2023, Standard for Performance Rating of Unitary Air Conditioning & Air Source Heat Pump Equipment, copyright 2020 (''AHRI 210/240–2023 (2020)'' [11]).

Following publication of the January 2023 RFI, AHRI and other relevant stakeholders, including DOE, participated in the development of two updated industry standards relevant to CAC/HPs, the AHRI 210/240–202X Draft and the AHRI 1600–202X Draft.[12] DOE understands that these drafts were commissioned primarily to address the issues raised by DOE in the January 2023 RFI, and secondarily to harmonize the AHRI industry standards with the DOE test procedures, which were last amended in the October 2022 Final Rule.

DOE has reviewed both drafts and determined that they allow for a more representative measurement of the efficiencies of CAC/HPs than the current Federal test procedure, without being unduly burdensome. Rather than make

[8] On January 1, 2023, use of appendix M1 became required for any representations—including compliance certifications—made with respect to the energy use, power, or efficiency of CAC/HPs. Prior to January 1, 2023, such representations were required to be based on the test procedure at appendix M to subpart B of 10 CFR part 430.

[9] *See* Table 4 of appendix M1 for the minimum ESP requirements for ducted blower-coil systems, including the 0.3 in. wc. requirement for space-constrained systems.

[10] A copy of AHRI 210/240–2008 can be obtained from AHRI, 2111 Wilson Boulevard, Suite 500, Arlington, VA 22201, USA, 703–524–8800, or by going to *www.ahrinet.org.*

[11] A copy of AHRI 210/240–2023 (2020) can be obtained from AHRI, 2111 Wilson Boulevard, Suite 500, Arlington, VA 22201, USA, 703–524–8800, or by going to *www.ahrinet.org.*

[12] Both draft standards are available in Docket No. EERE–2022–BT–TP–0028.

more amendments to the regulatory text of the current appendix M1 test procedure, DOE is proposing to adopt each industry standard respectively as the basis for an updated appendix M1 and a new appendix M2, similar to how AHRI 210/240–2008 was adopted as the basis of the current appendix M1 test procedure. Specifically, DOE is proposing to incorporate by reference AHRI 210/240–202X Draft, and the relevant standards it references: ANSI/ASHRAE 16–2016, ANSI/ASHRAE 37–2009, and ASHRAE 116–2010 as the basis for the updated appendix M1 test procedure. Similarly, DOE is proposing to incorporate by reference AHRI 1600–202X Draft, and the relevant standards it references ANSI/ASHRAE 16–2016, ANSI/ASHRAE 37–2009, and ASHRAE 116–2010 as the basis for the new appendix M2 test procedure. Incorporating each industry standard would enable DOE to better harmonize with the industry standards and eliminate manufacturer burden in certifying with separate test procedures.

1. AHRI 210/240–202X Draft

As previously discussed, AHRI and other relevant stakeholders, including DOE, worked to develop a revised AHRI 210/240 standard that would incorporate revisions to align with the October 2022 Final Rule, and additionally, seek to address the issues raised in the January 2023 RFI with broad stakeholder consensus. DOE understands that this new update is currently in draft form (*i.e.,* AHRI 210/240–202X Draft) and will supersede the current version of the standard, AHRI 210/240–2023 (2020). While AHRI 210/240–202X Draft does not introduce changes that would alter the measured efficiency of CAC/HPs, it does introduce new test provisions as compared to AHRI 210/240–2023 (2020), and addresses several issues that DOE raised in the January 2023 RFI. Section III.F of this NOPR includes further discussion of the changes that are reflected in AHRI 210/240–202X Draft.

In light of these updates to AHRI 210/240–202X Draft, DOE is proposing to amend its test procedure for CAC/HPs at appendix M1 by incorporating by reference AHRI 210/240–202X Draft. DOE intends to update its incorporation by reference to the final published version of AHRI 210/240–202X Draft in the final rule, unless the draft version is not finalized before the final rule or there are substantive changes between the draft and published versions, in which case DOE may adopt the substance of the AHRI 210/240–202X Draft or provide additional opportunity for comment on the substantive changes to the updated industry consensus standard. Specifically, DOE is proposing to utilize sections 3 (excluding 3.2.15, 3.2.19, 3.2.47, 3.2.52, 3.2.64, 3.2.79 and 3.2.80), 5, 6 (excluding 6.1.8, 6.2, 6.3, 6.4 and 6.5), 11, and 12 and appendices D, E, G, K, and L of the AHRI 210/240–202X Draft in the Federal test procedure for CAC/HPs at appendix M1.

Additionally, DOE is proposing additions and deletions to the incorporations by reference for the CAC/HP Federal test procedure to align with the references made within the AHRI 210/240–202X Draft. Currently, appendix M1 incorporates by reference: AMCA 210–2007,[13] AHRI 210/240–2008, AHRI 1230–2010,[14] ASHRAE 23.1–2010,[15] ANSI/ASHRAE 37–2009, and ASHRAE 116–2010. 10 CFR 430.3.

In the proposed test procedures at appendix M1, DOE is proposing to add an incorporation by reference to ANSI/ASHRAE 16–2016 and remove incorporations by reference to AMCA 210–2007, AHRI 210/240–2008, AHRI 1230–2010 and ASHRAE 23.1–2010. Therefore, DOE is proposing to incorporate by reference the AHRI 210/240–202X Draft, ANSI/ASHRAE 16–2016, ANSI/ASHRAE 37–2009, and ASHRAE 116–2010, at appendix M1.

2. AHRI 1600–202X Draft

In parallel to the AHRI 210/240–202X Draft, AHRI and other relevant stakeholders, including DOE, worked to develop a forward-looking AHRI test procedure that would act as the successor to the AHRI 210/240–202X Draft and be effective in the long-term (*i.e.,* AHRI 1600–202X Draft). DOE is proposing to establish a new test procedure for CAC/HPs at appendix M2 by incorporating by reference AHRI 1600–202X Draft. DOE intends to update its incorporation by reference to the final published version of AHRI 1600–202X Draft in the final rule, unless the draft version is not finalized before the final rule or there are substantive changes between the draft and published versions, in which case DOE may adopt the substance of the AHRI 1600–202X Draft or provide additional opportunity for comment on the substantive changes to the updated industry consensus standard. Specifically, DOE is proposing to utilize sections 3 (excluding 3.1.15, 3.1.19, 3.1.47, 3.1.52, 3.1.65, 3.1.80, and 3.1.81), 5, 6 (excluding 6.1.8, 6.2, 6.3, 6.4 and 6.5), 11, and 12 and appendices D, E, G, K, and L of the AHRI 1600–202X Draft in the Federal test procedure for CAC/HPs at appendix M2.

DOE is also proposing to incorporate by reference ANSI/ASHRAE 16–2016, ANSI/ASHRAE 37–2009, and ASHRAE 116–2010, which are referenced within AHRI 1600–202X Draft. Therefore, in total, DOE is proposing to incorporate by reference the AHRI 1600–202X Draft, ANSI/ASHRAE 16–2016, ANSI/ASHRAE 37–2009, and ASHRAE 116–2010, at appendix M2.

3. ANSI/ASHRAE 37–2009

ANSI/ASHRAE 37–2009, which provides a method of test for many categories of air conditioning and heating products and equipment, is referenced for testing CAC/HPs by both AHRI 210/240–202X Draft and the AHRI 1600–202X Draft. More specifically, section 5 and appendices C, D, E, I, and J of AHRI 210/240–202X and AHRI 1600–202X Draft refer to methods of test in ANSI/ASHRAE 37–2009. DOE currently incorporates by reference ANSI/ASHRAE 37–2009 in 10 CFR part 430, subpart B, and the current incorporation by reference applies to the current Federal test procedure for CAC/HPs specified at appendix M1. Given that AHRI 210/240–202X Draft references ANSI/ASHRAE 37–2009 for several test instructions, DOE has tentatively concluded that it is appropriate to maintain the existing incorporation by reference of ANSI/ASHRAE 37–2009 in appendix M1. Additionally, given that the AHRI 1600–202X Draft references ANSI/ASHRAE 37–2009 for several test instructions, DOE is proposing to additionally incorporate by reference ANSI/ASHRAE 37–2009 for use with appendix M2.

4. ANSI/ASHRAE 16–2016

ANSI/ASHRAE 16–2016, which provides a method of test for rating Room Air Conditioners, Packaged Terminal Air Conditioners, and Packaged Terminal Heat Pumps, is referenced for testing CAC/HPs by both

[13] ANSI/AMCA 210–2007, ANSI/ASHRAE 51–2007, (''AMCA 210–2007'') Laboratory Methods of Testing Fans for Certified Aerodynamic Performance Rating, ANSI approved Aug. 17, 2007. A copy of AMCA 210–2007 can be purchased from the Air Movement and Control Association International Inc. (''AMCA'') website at *www.amca.org/store/index.php*.

[14] ANSI/AHRI 1230–2010 with Addendum 2, (''AHRI 1230–2010''): 2010 Standard for Performance Rating of Variable Refrigerant Flow (''VRF'') Multi-Split Air-Conditioning and Heat Pump Equipment, ANSI approved Aug. 2, 2010. A copy of AHRI 1230–2010 can be obtained from AHRI, 2111 Wilson Boulevard, Suite 500, Arlington, VA 22201, USA, 703–524–8800, or by going to *www.ahrinet.org*.

[15] ANSI/ASHRAE 23.1–2010, (''ASHRAE 23.1–2010''): Methods of Testing for Rating the Performance of Positive Displacement Refrigerant Compressors and Condensing Units that Operate at Subcritical Temperatures of the Refrigerant, ANSI approved Jan. 28, 2010. A copy of ASHRAE 23.1–2010 can be obtained from the ASHRAE website at *www.ashrae.org/resources--publications.*

the AHRI 210/240–202X Draft and the AHRI 1600–202X Draft. More specifically, section 5.1.1 of AHRI 210/240–202X Draft and AHRI 1600–202X Draft refer to testing of non-ducted CAC/HPs from provisions in ANSI/ASHRAE 16–2016, or by using a combination of provisions in ANSI/ASHRAE 37–2009 and ANSI/ASHRAE 116–2016. Currently, ANSI/ASHRAE 16–2016 is not incorporated by reference in appendix M1. DOE has tentatively concluded that testing conducted per ANSI/ASHRAE 16–2016 for non-ducted CAC/HPs, will not impact ratings in comparison to testing conducted per provisions in ANSI/ASHRAE 37–2009 and ANSI/ASHRAE 116–2010. Thus, given that the AHRI 210/240–202X Draft and AHRI 1600 202X Draft refer to ANSI/ASHRAE 16–2016 as an option for testing of non-ducted CAC/HPs, and that it does not impact ratings, DOE has tentatively concluded that it is appropriate to incorporate by reference ANSI/ASHRAE 16–2016 for appendices M1 and M2.

5. ANSI/ASHRAE 116–2010

ANSI/ASHRAE 116–2010, which provides a method of test for unitary air conditioners and heat pumps with a cooling capacity of 65,000 Btu/h and less, is referenced for testing CAC/HPs by both AHRI 210/240–202X Draft and AHRI 1600–202X Draft. More specifically, sections 5, 6, 8, and 11 and appendices D and E of AHRI 210/240–202X Draft and AHRI 1600–202X Draft refer to methods of test in ANSI/ASHRAE 116–2010. Given that AHRI 210/240–202X Draft references ANSI/ASHRAE 116–2010 for several test instructions, DOE has tentatively concluded that it is appropriate to maintain the existing incorporation by reference of ANSI/ASHRAE 116–2010 in appendix M1. Additionally, given that the AHRI 1600–202X Draft references ANSI/ASHRAE 116–2010 for several test instructions, DOE is proposing to additionally incorporate by reference ANSI/ASHRAE 116–2010 for use with appendix M2.

D. Proposed CAC/HP Test Procedure

As discussed, EPCA requires that test procedures for each type of covered product, including CAC/HPs, not be unduly burdensome to conduct and be reasonably designed to produce test results that reflect energy efficiency, energy use, and estimated operating costs during a representative average use cycle or period of use. (42 U.S.C. 6293(b)(1)(A))

In this NOPR, DOE is proposing to maintain the current efficiency metrics of SEER2 and HSPF2 in appendix M1 and is proposing to reference AHRI 210/240–202X Draft in appendix M1 for measuring the existing metrics. DOE has tentatively determined that the proposed amendments to appendix M1 would not affect the measured efficiency of CAC/HPs or require retesting solely because of DOE's adoption of the proposed amendments to the appendix M1 test procedure, if made final. Additionally, DOE is proposing to establish a new test procedure at appendix M2 that would adopt the AHRI 1600–202X Draft, including the newly proposed SCORE and SHORE metrics. Use of appendix M2 would not be required until the compliance date of any amended standards denominated in terms of the proposed new metrics for appendix M2, should such standards be adopted.

If finalized versions of AHRI 210/240 and AHRI 1600 are not published before the test procedure final rule, or if there are substantive changes between the drafts and published versions of the standards that are not supported by stakeholder comments in response to this NOPR, DOE may adopt the substance of the AHRI 210/240–202X Draft and AHRI 1600–202X Draft or provide additional opportunity for comment on the final version of that industry consensus standard.

Specifically, at appendix M1, DOE is proposing to require the following sections of the AHRI 210/240–202X Draft: sections 3 [16], 5, 6 [17], 11, and 12, and appendices D, E, G, K, and L. At appendix M2, DOE is proposing to require the following sections of the AHRI 1600–202X Draft: sections 3 [18], 5, 6 [19], 11, and 12 and appendices D, E, G, K and L.

Further, at both appendix M1 and appendix M2, DOE is proposing to incorporate by reference the following: ANSI/ASHRAE 37–2009; ANSI/ASHRAE 16–2016; and ANSI/ASHRAE 116–2010.

Issue 1: DOE requests feedback on its proposal to revise appendix M1 to incorporate by reference AHRI 210/240–202X Draft for measuring the existing metrics, SEER2 and HSPF2.

Issue 2: DOE requests feedback on its proposal to establish a new appendix M2, which would incorporate by reference AHRI 1600–202X Draft to determine the SCORE and SHORE metrics.

E. Efficiency Metrics

As discussed, DOE proposes to update the current Federal test procedure for CAC/HPs at appendix M1 consistent with the most recent draft version of the relevant industry consensus test procedure, AHRI 210/240–202X Draft. DOE is also proposing a new Federal test procedure at 10 CFR part 430, subpart B, appendix M2, consistent with the draft version of the industry consensus test procedure, AHRI 1600–202X Draft. Sections III.E.1 and III.E.2 indicate which metrics are applicable for appendices M1 and M2, respectively.

1. Metrics Applicable to Appendix M1

In the updated appendix M1, DOE proposes to maintain the current energy efficiency metrics (*i.e.,* energy efficiency ratio 2 (''EER2''), SEER2, and HSPF2), and to define a new optional metric: the peak load coefficient of performance (''COP_{peak}''), applicable to CHPs (*see* details in section III.F.2.d of this document). The proposed revisions to appendix M1 to align with the most recent draft of AHRI 210/240–202X Draft maintain the existing energy efficiency metrics, and DOE has tentatively determined that testing under the proposed appendix M1 would be consistent with the existing test procedure and there would be no impact on measured efficiencies.

2. Metrics Applicable to Appendix M2

As previously discussed in this NOPR, the proposed appendix M2 will introduce new integrated cooling and integrated heating efficiency metrics, namely SCORE and SHORE, respectively. Unlike SEER2 and HSPF2, which are seasonal energy efficiency descriptors, SCORE and SHORE are

[16] DOE is not proposing to include the following provisions from section 3 of AHRI 210/240–202X Draft because the terms are either defined in appendix M1, or are not needed for the proposed DOE test procedure: 3.2.15 (Double-duct system), 3.2.19 (Gross Capacity), 3.2.47 (Oil Recovery Mode), 3.2.52 (Published Rating), 3.2.64 (Standard Filter), 3.2.80 (Unitary Air-conditioner), and 3.2.81 (Unitary Heat Pump).

[17] DOE is not proposing to include the following provisions from section 6 of AHRI 210/240–202X Draft because the provisions are either defined in 10 CFR 429.16, or are not needed for the proposed DOE test procedure: 6.1.8 (Tested Combinations or Tested Units), 6.2 (Application Ratings), 6.3 (Publication of Ratings), 6.4 (Ratings), and 6.5 (Uncertainty and Variability).

[18] DOE is not proposing to include the following provisions from section 3 of AHRI 1600–202X Draft because the terms are either defined in appendix M1, or are not needed for the proposed DOE test procedure: 3.1.15 (Double-duct System), 3.1.19 (Gross Capacity), 3.1.47 (Oil Recovery Mode), 3.1.52 (Published Rating), 3.1.65 (Standard Filter), 3.1.80 (Unitary Air-conditioner), and 3.1.81 (Unitary Heat Pump).

[19] DOE is not proposing to include the following provisions from section 6 of AHRI 1600–202X Draft because the provisions are either defined in 10 CFR 429.16, or are not needed for the proposed DOE test procedure: 6.1.8 (Tested Combinations or Tested Units), 6.2 (Application Ratings), 6.3 (Publication of Ratings), 6.4 (Ratings), and 6.5 (Uncertainty and Variability).

integrated metrics that include off-mode power, $P_{W,OFF}$. Hence, appendix M2 will not require separate representations for off-mode power.

DOE is proposing to retain EER2 in appendix M2, with EER2 evaluated in the same way as it was in appendix M1. DOE is also proposing the determination of an optional metric, COP_{peak}, as discussed in section III.E.1 of this document, in appendix M2.

F. Near-Term Changes in the CAC/HP Test Procedure

The following sections discuss issues that affect the CAC/HP test procedure in the near-term—*i.e.,* they will be effective 180 days after publication of the final rule. As previously explained, these near-term revisions are implemented at appendix M1 via incorporation by reference of the relevant industry consensus test procedure, AHRI 210/240–202X Draft. DOE has reviewed AHRI 210/240–202X Draft and has concluded that it satisfies the EPCA requirement that test procedures should not be unduly burdensome to conduct and should be representative of an average use cycle. (42 U.S.C. 6293(b)(1)(A)) These near-term amendments in appendix M1 would not alter the measured efficiency of CAC/HPs in terms of the current cooling and heating test metrics, SEER2 and HSPF2, respectively.

DOE clarifies that while all issues discussed subsequently are considered near-term, they are also part of the long-term CAC/HP test procedure—*i.e.,* these revisions are also included in AHRI 1600–202X Draft, which DOE is proposing to incorporate by reference at appendix M2. As such, when discussing these near-term changes, DOE makes references to both AHRI 210/240–202X Draft and AHRI 1600–202X Draft.

1. Representativeness of Fixed Speed Testing for Variable Speed (VS) Systems

(a) Background

Appendix M1 uses a steady-state test concept where test room conditions are kept within narrow operating tolerances for each test point, and the CAC/HP system is manually controlled to operate at the specified compressor speed and airflow rate for each test point. In the October 2022 Final Rule, several stakeholders encouraged DOE to review ways to improve the representativeness of the test procedures for CAC/HPs (especially variable speed), particularly to examine test procedures where the unit operates under its own native controls in responding to conditioning loads (*i.e.,* load-based testing).[20] DOE stated in the October 2022 Final Rule that the rulemaking had been initiated only to address a limited number of known issues in the current appendix M1 method, including those raised through the test procedure waiver process. 87 FR 64554, 64554. However, DOE also responded that in order to satisfy the 7-year lookback requirement (see 42 U.S.C. 6293(b)(1)(A)), a future rulemaking may address more comprehensively the issues raised by the commenters. (*Id.*)

As discussed in section I.B of this document, on January 24, 2023, DOE published the January 2023 RFI in order to collect data and information regarding the need to amend the test procedures for CAC/HPs, to address issues raised by commenters in the October 2022 Final Rule, and in satisfaction of the 7-year review requirement specified in EPCA. (42 U.S.C. 6293(b)(1)(A)). 87 FR 64554, 64554. In the January 2023 RFI, DOE requested comments, information, and data pertaining to the consideration of load-based testing methodologies under development by various organizations and whether certain aspects of these methodologies might be adopted into the DOE test procedure. 88 FR 4091, 4098–4101. Among the load-based testing methodologies summarized by DOE in the January 2023 RFI was the first edition of Canadian Standard Association (''CSA'') EXP07:19, ''Load-based and climate-specific testing and rating procedures for heat pumps and air conditioners'' (''EXP07''). 88 FR 4091, 4095. DOE notes that EXP07 was superseded by CSA SPE–07:23 [21] (''SPE07'') in January 2023, an updated version of EXP07 with changes made based on comments received during a technical review period.

(b) Comments Received

In response to the January 2023 RFI, DOE received a variety of comments related to various aspects of load-based testing. The comments are summarized in the following sub-sections, segregated by topic as appropriate.

(1) Repeatability and Reproducibility

In the January 2023 RFI, DOE presented several initiatives and programs that were investigating, researching, and/or developing load-based test methods. 88 FR 4091, 4095–4098. DOE requested data and information to quantify which of these load-based methods—and any other that DOE is not aware of—had higher repeatability and reproducibility compared to the others, and also compared to fixed-speed tests. 88 FR 4091, 4099.

In response, Samsung, Carrier, Daikin, Rheem, AHRI, and Lennox all commented that available test data have shown that the repeatability and reproducibility of load-based methods is not on par with current fixed-speed testing used for regulatory purposes. (Samsung, No. 11 at p. 1; Carrier, No. 5 at pp. 2–3; Daikin, No. 16 at pp. 2–3; Rheem, No. 12 at pp. 2–3; AHRI, No. 14 at pp. 8–9; Lennox, No. 6 at p. 3) Samsung asserted that adopting something unproven, like the load-based test methods, may create a chaotic situation in the marketplace, and will create additional test burden for manufacturers since load-based testing methods do not address alternative efficiency determination methods (''AEDMs''). (Samsung, No. 11 at p. 1)

Carrier referred to the Technology Collaboration Program of Energy Efficient End-use Equipment, International Energy Efficiency (''4E IEA'') [22] and AHRI 8026 [23] initiatives, which showed that load-based testing of the same units across different facilities showed high variability, and commented that more work and research needs to be done in order to reduce this variability before adopting load-based testing for determining energy efficiency of CAC/HP systems. (Carrier, No. 5 at pp. 2–3) Daikin also commented that until all issues pertaining to load-based testing are fully vetted, there would be significant problems with repeatability and reproducibility. (Daikin, No. 16 at pp. 2–3) Daikin mentioned several items that contribute to variability in load-

[20] A load-based test method differs from the steady-state test method currently used in DOE test procedures for air conditioning and heat pump equipment. In a steady-state test method, the indoor room is maintained at a constant temperature throughout the test. In this type of test, any variable speed or variable-position components of air conditioners and heat pumps are set in a fixed position, which is typically specified by the manufacturer. In contrast, a load-based test has the conditioning load applied to the indoor room using a load profile that approximates how the load varies for units installed in the field. In this type of test, an air conditioning system or heat pump is allowed to automatically determine and vary its control settings in response to the imposed conditioning loads rather than relying on manufacturer-specified settings.

[21] SPE07 is available for download at: *wwwcsagroup.org/store/product/CSA%20SPE-07:23/.*

[22] ''AC/HP Test Methods Investigative Testing: Phase 2 Preliminary Findings'' 4E IEA presentation (May 7, 2021). *See www.iea-4e.org/wp-content/uploads/2021/08/AC-HP-Test-Methods-Phase-2-key-Findings-2021-08-06-CLEAN.pdf.*

[23] Dhillon, P., Horton, W.T., & Braun, J.E. (2022). AHRI 8026—Repeatability and Reproducibility Assessment of CSA EXP07:19 and AHRI 210–240:2023. Air Conditioning, Heating, and Refrigeration Institute.

based testing, such as the controller (room thermostat), controller setup, control modifications in the test chamber, and the application of the load. (*Id.* at pp. 2–3) Daikin also requested that stakeholders thoroughly evaluate the secondary capacity check process during load-based testing, and compare that with the accuracy, repeatability, and reproducibility of conventional fixed-speed testing. (Daikin, No. 16 at p. 12)

Rheem and AHRI both referred to the results of AHRI 8026. (Rheem, No. 12 at pp. 2–3; AHRI, No. 14 at pp. 8–9) Rheem commented that per AHRI 8026, the transient conditions during load-based testing cause poorer repeatability and reproducibility in comparison to fixed-speed testing currently in appendix M1. (Rheem, No. 12 at pp. 2–3) Rheem further stated that even with appendix M1 testing, reproducibility of transient components like cyclic degradation and defrost can be challenging. (*Id.*) AHRI commented that AHRI 8026 results revealed concerns when it comes to repeatability and reproducibility of performance metrics of load-based testing. (AHRI, No. 14 at pp. 8–9) Further, AHRI noted that there are no analyses of control system parameter variability available for load-based testing, and that such analyses would require significant investments in lab facilities and technical training and none of the load-based testing methods address the use of AEDMs. (*Id.)* Similarly, Lennox mentioned several items that affect the repeatability and reproducibility of load-based testing, including the varying degrees of test burden in the different methods, changes required to lab facilities to accommodate load-based testing, interaction between the unit under test and the lab facility, and how the lab facility affects the load-based tests. (Lennox, No. 6 at p. 3) Lennox expressed concern over the fact that labs may need to significantly invest in their facilities and resources if their present setups were found to positively or negatively influence load-based test results. (*Id.)*

NEEA commented that a pre-defined load test [24] may have greater repeatability and reproducibility in comparison to an adaptive load test, because multiple variables need to be controlled for an adaptive load, and there are several interactive effects between unit performance and test lab conditions. (NEEA, No. 13 at p. 6) NEEA referred to the 4E IEA program,[25] stating that preliminary results from phase 4 of 4 are expected to be available by mid-summer 2023, with full study results to be released at the end of 2023 or early in 2024. (*Id.*)

(2) Field Performance

In the January 2023 RFI, DOE requested data showing that load-based testing was more representative of field performance, in comparison to conventional fixed-speed and fixed-setting test procedures. 88 FR 4091, 4099. DOE also requested data that would indicate whether CAC/HP units that performed poorly in the lab, when tested using load-based methods, also performed poorly in the field. *Id.*

Carrier commented that it was not aware of publicly available data showing that load-based test methods are more or less representative than fixed-speed and fixed-setting test procedures. (Carrier, No. 5 at p. 3) Carrier further commented that even though there is value in verifying the operation of variable speed systems, it was unclear if a load-based test method would provide more representative tests in comparison to fixed-speed testing with a controls verification procedure (''CVP'') to confirm unit operation at the speeds specified in the fixed-speed tests. (*Id.)* Similarly, Daikin stated that even though several studies are being conducted, there is a general lack of information and data to substantiate whether load-based testing or fixed-speed testing is more representative of real-world scenarios. (Daikin, No. 16 at p. 3) Daikin expressed concern over the fact that load-based test methods, such as SPE07, do not account for real-world scenarios when a CAC/HP is installed with a controller (or room thermostat) of a different brand than the manufacturer of the CAC/HP. (*Id.)* Daikin commented that if controller operation is central to load-based testing, then smart thermostat manufacturers would also need to provide ratings when their product is matched with another manufacturer's CAC/HP, similar to the process followed by independent coil manufacturers (''ICMs'') for representing the ratings of their indoor coils with different combinations of other manufacturers' outdoor coils. (*Id.)*

Daikin also commented that load-based test methods currently do not address AEDM calculation methods for non-tested combinations (''NTCs''), nor do they have a method for ICMs to rate their indoor coil products with an outdoor unit that has been tested using load-based methods. (*Id.)*

Rheem commented that while it believed more studies are needed for evaluating the representativeness of load-based methods, field performance is very dependent on installation practices. (Rheem, No. 12 at p. 3) The CA IOUs commented that the current appendix M1 test procedure uses fixed compressor speeds and air volume rates with fixed indoor and outdoor temperature conditions, and is thus not representative of field use, indicating that the energy efficiencies may be misinterpreted. (CA IOUs, No. 10 at pp. 1–2)

(3) Test Burden

A critical component of load-based testing is the relevant burden(s) associated with the testing—*i.e.,* total testing time, time needed for control system learning, number of official test points, time required to transition between test points, upgrades to laboratory equipment, and cost and time associated with training technicians to be able to conduct load-based testing. In the January 2023 RFI, DOE requested comment from stakeholders on information pertaining to the aforementioned test burdens. 88 FR 4091, 4099.

In response, Carrier, Daikin, and Rheem commented that the test burden of load-based testing is generally more than that of fixed-speed testing. (Carrier, No. 5 at pp. 3–4; Daikin, No. 16 at pp. 3–4; Rheem, No. 12 at pp. 3–4) Regarding costs, Carrier commented that lab investments will be needed to emulate Virtual Building Load (''VBL''),[26] and Rheem commented that even though predicting the cost impact of emerging load-based methods is difficult, there will definitely be costs associated with changes to test chambers and equipment that manufacturers will have to bear. (Carrier, No. 5 at pp. 3–4; Rheem, No.

[24] In its comment, NEEA defined a pre-defined load test as those where the unit under test (UUT) is subjected to pre-defined sensible or latent loads, and stated that the 4E program and the DOE CCHP Tech Challenge were examples of such a load based test method. They defined adaptive load test methods as those where a constant or variable sensible and latent is applied to the UUT, but the magnitude of the load can be altered, based on unit behavior, and stated that the SPE07 was an example of such a method.

[25] ''AC/HP Test Methods Investigative Testing: Phase 2 Preliminary Findings'' 4E IEA presentation (May 7, 2021). *See: www.iea-4e.org/wpcontent/uploads/2021/08/AC-HP-Test-Methods-Phase-2-key-Findings-2021-08-06-CLEAN.pdf.*

[26] Virtual Building Load is a load-based or native controls test procedure during which the software that controls the indoor test room conditions (*i.e.,* operates the indoor room reconditioning system) is programmed to mimic the response of building heating or cooling in real time by monitoring the capacity of the unit under test and adjusting the indoor room conditions according to the virtual building model. The virtual building model defines the time-dependent rate of change of the indoor room temperature and humidity conditions as a function of the target building load and the measured capacity of the tested system.

12 at pp. 3–4) Carrier and Daikin both commented that load-based testing methods would require more time to conduct due to the higher number of tests involved. (Carrier, No.5 at pp. 3–4; Daikin, No.16 at pp. 3–4)

Daikin also stated that during new product development, manufacturers only have to do a subset of appendix M1 tests, often iteratively, because results of those subsets are enough to inform the manufacturer of the design changes needed. (Daikin, No. 16 at pp. 3–4) Daikin commented that due to lack of experience with load-based methods such as SPE07, it would not be possible to do quick assessments like these. (*Id.* at pp. 3–4) Finally, Daikin stated that changes to refrigerant regulations that will occur in 2023 will require a full redesign of the products, and manufacturers may not be able to accomplish that in a timely manner using load-based methods. (*Id.*)

Rheem referred to the 4E IEA project report, in which it was estimated that the additional test burden due to the Target Compensation Load method will have a 60-percent to 250-percent increase in test burden. (Rheem, No. 12 at pp. 3–4) Rheem commented that load-based test methods would require changes to control schemes, additional test setups, and additional equipment, due to rapidly changing loads inside the chamber. (*Id.*) Rheem referred to several research studies [27] [28] that showed load-based test methods are influenced by the thermal inertia of the psychrometric chambers in which the tests are conducted; thus, adaptation of the control system to this thermal inertia may be a time-consuming process. (*Id.*) AHRI stated that even though the value of load-based testing remains unknown, the burden has been quantified. (AHRI, No. 14 at p. 5)

In summary, all comments received indicated that the test burden for load-based testing will be higher than that of conventional fixed-speed testing laid out in appendix M1.

[27] Cremaschi, L., & Perez Paez, P. (2017). Experimental feasibility study of a new load-based method of testing for light commercial unitary heating, ventilation, and air conditioning (ASHRAE RP–1608). Science and Technology for the Built Environment, 23(7), 1178–1188. Available at *www.tandfonline.com/doi/full/10.1080/23744731.2016.1274628.*

[28] Göbel, S.A., Zottl, A., Noack, R., Mock, D., Wachau, A., Vering, C., & Müller, D. (2022, August). How to calibrate heat pump test stands for load-based testing—Towards technology-neutral prescriptions [Paper presentation]. 14th International Conference on Applied Energy, ICAE22, August 8–11, 2022, Bochum, Germany. Available at *www.ebc.eonerc.rwth-aachen.de/go/id/dncb/file/855717?lidx=1.*

(4) Thermostat Selection and Built-In Control Firmware

Thermostats (*i.e.,* ''control systems'') can vary significantly in their control algorithms and communication with the unit under test. Thus, thermostat selection can play a key role in the results of load-based tests. In the January 2023 RFI, DOE requested comment on several impacts of thermostats with respect to load-based testing, including the observed range of performance of the same unit tested with different thermostats, and consideration of whether a thermostat needs to be certified as part of the tested combination. 88 FR 4091, 4099. DOE also requested comment on what percentage of thermostats may be updated remotely versus in the field, and how unit behavior in the field depends on thermostats shipped with the unit versus those purchased from third-party suppliers. (*Id.*)

In response to this issue, DOE received comments from several stakeholders. Carrier and Rheem commented that thermostats have a big impact on load-based test results. (Carrier, No. 5 at p. 4; Rheem, No. 12 at p. 4) Carrier commented that since the majority of HVAC systems in the market are not installed with a manufacturer's thermostat, it would not be feasible for manufacturers to test with the different thermostats available. (Carrier, No. 5 at p. 4) Carrier further stated that only variable speed systems shipped with the manufacturer's thermostat should have certification requirements. (*Id.*) The Joint Advocates and NYSERDA encouraged DOE to require certification of thermostats as part of the tested combination. (Joint Advocates, No. 8 at p. 2; NYSERDA, No. 9 at pp. 6–7) Specifically, the Joint Advocates encouraged DOE to investigate how the performance of single-stage, two-stage, and variable speed equipment is impacted by integrations of different thermostats, and to develop testing requirements for ensuring that the tested thermostat is representative of the one selected in the field. (Joint Advocates, No. 8 at pp. 2–3)

NYSERDA commented that thermostat selection will be integral to a CVP, which verifies that the manufacturer's supplemental testing instructions for setting critical parameters during fixed-speed testing are within the range of critical parameters that the system would utilize when operating under its native controls. (NYSERDA, No. 9 at pp. 6–7) NYSERDA further commented that communicating systems may only be compatible with certain thermostats; hence, DOE should have a regulatory requirement that discourages pairing such systems with third-party thermostats. (*Id.*) However, NYSERDA recognized that in some situations, such as for blower coil indoor units, the system has communication technology built in that allows the use of any thermostat, which may not require certification with external thermostats. (*Id.* at p. 7) NYSERDA concluded that the actual firmware governing unit behavior is built into the unit, and not into the thermostat, meaning that updated testing would be required only in instances when the updated firmware results in an updated model number. (*Id.)* AHRI stated that certification requirements will be complicated with thermostats, especially when utilizing those that are not specified by the manufacturer. (AHRI, No. 14 at pp. 9–10) AHRI also stated that different thermostats will give different load-based test results, and referred to an article stating that smart thermostats were only being used by 16 percent of households. (*Id.*)

Daikin commented that due to the limited time allowed for submitting comments in response to the January 2023 RFI, it did not have thermostat-associated data to share with DOE other than that from its own ''Daikin One'' thermostat. (Daikin, No. 16 at pp. 4–5) Daikin stated that several issues pertain to thermostat selections, making load-based testing unrepresentative of real-world situations; for instance, Daikin questioned whether, in the case of systems installed with smart thermostats like Nest or EcoBee, the unit manufacturer will be responsible for rating the system if the thermostat receives a remote firmware upgrade. (*Id.*)

Several commenters referred to Annex I of SPE07, which outlines a Thermostat Environment Emulator (''TEE'') developed by Purdue University that is a thermostat enclosure aimed at providing controlled airflow and temperature distribution to the air sensed by the thermostat. (Daikin, No. 16 at pp. 4–5; Joint Advocates, No. 8 at p. 3; NYSERDA, No. 9 at p. 7) Specifically, Daikin commented that the TEE demonstrated that thermostat location is an integral part of unit performance, but such an enclosure is not representative of real-world installations. (Daikin, No. 16 at pp. 4–5) In contrast, the Joint Advocates encouraged DOE to adopt something similar to the TEE in its test procedure so that reproducibility issues occurring between the various indoor rooms of psychrometric chambers (that conduct

load-based testing) may be mitigated. (Joint Advocates, No. 8 at p. 3)

Rheem pointed out that temperature sensors inside thermostats may not be as responsive or accurate as laboratory-grade temperature sensors, and because of this, temperature offsets are often necessary for tests done under native controls. (Rheem, No. 12 at p. 4) Rheem further commented that since these offsets may be influenced by the air flow rate over the thermostat, thermostat location, and orientation, there may be a requirement to dynamically modify this offset as the load-based test proceeds. (*Id.*) Rheem stated that remote update of unit/controller firmware is a relatively new feature, and therefore not as widely available as firmware updates done in the field by service technicians. (*Id.*)

(5) Utilizing Distinct Test Methods for Different Purposes

In the January 2023 RFI, DOE requested comment on whether there are any load-based methods that are being used for regulatory or voluntary incentive-based programs. 88 FR 4091, 4100. Rheem, AHRI, and NYSERDA all commented that they are unaware of any load-based methods being used for the aforementioned purposes. (Rheem, No. 12 at p. 4; AHRI, No. 14 at p. 10; NYSERDA, No. 9 at p. 9) Daikin commented that in 2024, U.S. Environmental Protection Agency (''EPA'') ENERGY STAR® Version 6.1 specifications (''ENERGY STAR Spec V6.1'') [29] will be required for the Canada Greener Homes Program, even though currently it is an optional load-based method applicable only to cold climate heat pumps (''CCHPs''). (Daikin, No. 16 at p. 5) Daikin pointed out that due to the resources and efforts required to develop new products with low global warming potential (''GWP'') refrigerants like R32, Daikin doubts it will engage in any non-mandatory load-based testing. (*Id.*) NYSERDA referred to three initiatives associated with load-based testing, namely (1) the Canadian market transformation roadmap presented at the 2018 Energy and Mines Ministers' Conference,[30] (2) British Columbia's 2022 Heat Pump Technology Attraction Strategy,[31] and (3) a plan for differentiating advanced heat pumps using load-based testing criteria in the Northeast Energy Efficiency Partnerships (''NEEP'') qualified product list.[32] (NYSERDA, No. 9 at pp. 8–9) NYSERDA encouraged incentive-based approaches for advanced heat pumps that include: (1) a CVP to identify unit operation under native controls, (2) using regional HSPF2 to differentiate advanced heat pumps, and (3) prescribing capacity maintenance and coefficient of performance (''COP'') levels at 5 °F, similar to those in the ENERGY STAR Spec V6.1 requirements. (*Id.* at p. 9)

(6) Comparison of Test Conditions of Appendix M1 and SPE07

In the January 2023 RFI, DOE provided a detailed explanation of the first edition of EXP07. 88 FR 4091, 4095. As previously mentioned, EXP07 was superseded by SPE07, an updated version of EXP07 with changes made based on comments received during a technical review period in January 2023. SPE07 is a load-based methodology where the unit under test is allowed to respond to a thermostat installed in the return air stream, while the indoor room conditioning equipment control is used to adjust that temperature (to represent heating or cooling conditioning load), mimicking the response of a typical building. The test sequences through a set of representative outdoor room conditions. In the January 2023 RFI, DOE pointed out that these test conditions differ from those laid out in appendix M1. 88 FR 4091, 4100. Due to these differences, DOE requested comment on how unit performance would compare when tested using the SPE07 test conditions (indoor as well as outdoor) and the appendix M1 test conditions. *Id.* DOE further requested feedback on the pros and cons of potentially revising the test conditions in appendix M1. *Id.*

AHRI pointed out that the concept of SPE07 is interesting from a research perspective but not suitable for regulatory purposes. (AHRI, No. 14 at p. 5) AHRI noted that the seasonal COP metrics in SPE07 are climate zone dependent, and there is no metric that calculates unit performance at a national average level. (AHRI, No. 14 at pp. 5–6) AHRI pointed to 42 U.S.C. 6291(22), to state that the seasonal COP metrics cannot be adopted by DOE in appendix M1 as the efficiency descriptors. (*Id.* at p. 6) Further, AHRI commented that SPE07 is currently not applicable to coil-only systems, which means that if adopted, the process of certification and enforcement for split systems would need to be overhauled. (*Id.*) AHRI also pointed that SPE07 currently does not address AEDMs, which implies that a regulatory regime under SPE07 would create significant test burden due to the large number of rated combinations of split-system units. (*Id.*) AHRI referred to the testing reporting requirements in appendix M1 for variable speed mini and multi-splits, stating that SPE07 does not properly define requirements for established ratings for these products. (*Id.* at p.7) Finally, AHRI cited a section of 42 U.S.C 6293(b)(3) to point out that test procedures should not be unduly burdensome to conduct.[33] (*Id.*) AHRI commented that its commentary is limited to SPE07, stating that it is the most developed and established load-based methodology, but AHRI still does not see a viable pathway for SPE07 moving forward. (*Id.*)

Daikin and Rheem both commented that since appendix M1 and SPE07 have different performance metrics, their ratings cannot be compared. (Daikin, No. 16 at p. 5; Rheem, No. 12 at pp. 4–5) Daikin commented that it lacks data that can be shared comparing appendix M1 and SPE07 testing. (Daikin, No. 16 at p. 5) Daikin pointed out that the different indoor dry bulb and wet bulb temperature setpoints in appendix M1 and SPE07 would lead to different efficiencies, and the higher number of test points in SPE07 adds to test burden. (Daikin, No. 16 at p. 5) Daikin referred to how the tolerance of 10 percent was chosen when commercial HVAC products moved to a seasonal metric (integrated energy efficiency ratio (''IEER'')), from a peak load metric (*i.e.,* EER), rather than 5 percent, indicating that the tolerance for certified ratings would have to be increased if DOE adopted a load-based testing method for regulatory purposes. (*Id.* at p. 6)

Rheem referred to a research paper [34] to back its claim that relative rankings

[29] Version 6.1 of the ENERGY STAR specification for CAC/HPs, revised in January 2022, can be found at *www.energystar.gov/products/spec/central_air_conditioner_and_air_source_heat_pump_specification_version_6_0_pd.*

[30] NYSERDA referred to p. 32 of the 2018 report titled ''Paving the Road to 2030 and Beyond: Market transformation road map for energy efficient equipment in the building sector.'' Available at *www2.gov.bc.ca/assets/gov/farming-natural-resources-and-industry/electricity-alternative-energy/energy-efficiency/18-00072-nrcan-road-map-eng.pdf.*

[31] NYSERDA referred to pages 20, 25, and 26 of the Vancouver Energy Commission's *BC Heat Pump Technology Attraction Strategy,* available at *vancouvereconomic.com/wp-content/uploads/2022/11/11-2022-BC-Heat-Pump-Strategy-Report-Web-1.1.pdf.*

[32] NYSERDA referred to page 14 of the ''Advanced Heat Pump White paper,'' available at *www.mwalliance.org/sites/default/files/media-document/Advanced%20HP%20Whitepaper%20v1.13.pdf.*

[33] From this comment, DOE considers that AHRI wanted to make the point that SPE07, as it currently stands, is unduly burdensome.

[34] Dhillon, P., Horton, W. T., & Braun, J. E. (2022). Comparison of residential heat pump heating seasonal performance based on load-based and steady-state testing methodologies. ASHRAE Transactions, 128(1), 181–189. Available at

Continued

of SPE07 and appendix M1 are impossible. (Rheem, No. 12 at pp. 4–5) Rheem further pointed out that since the indoor dry bulb and wet bulb temperature in appendix M1 are the same for all tests, the time for testing is optimized. (*Id.*) Similarly, Carrier commented that research currently in progress would enable a comparison of the ranking of units when tested with appendix M1 and SPE07, but any conclusions cannot be reached currently. (Carrier, No. 5 at pp. 4–5) Samsung supported AHRI's comment on SPE07 and stated that load-based testing is not currently at a stage where it may be adopted as the mandatory test procedure by DOE. (Samsung, No. 11 at p. 1)

BC Hydro strongly encouraged DOE to adopt SPE07 as the next test procedure for CAC/HPs and referred to four NEEA papers [35] that highlighted lessons learned from EXP07 testing that prompted the update to SPE07. (BC Hydro, No. 15 at pp. 1–2) Similarly, both the CA IOUs and the Joint Advocates referred to a NEEP representativeness project [36] and encouraged DOE to update the CAC/HP test procedure on the basis of those results. (CA IOUs, No. 10 at p. 2; Joint Advocates, No. 8 at p. 2) NYSERDA commented that more work needs to be done in order to consider the VBL approach (used as the basis of testing in SPE07), and specifically referred to additional efforts needed to ensure the repeatability and reproducibility of this method—namely, field data to validate lab data, lab-to-lab round robin testing, and an uncertainty analysis method that accounts for the unit under test's embedded controls and thermostat. (NYSERDA, No. 9 at p. 6)

Regarding test conditions, NYSERDA commented that it did not have specific analysis about the overall outdoor conditions but did point out: (1) SPE07 focuses on more extreme outdoor conditions; (2) different rankings of appendix M1 metrics and load-based testing results are mainly due to the influence of the unit's native controls on operation and any minor changes to the appendix M1 test conditions will not have a big impact on rankings; and (3) the addition of a hot-dry SEER2 rating would better capture performance at extreme climates.[37] (NYSERDA, No. 9 at p. 10) AHRI recommended that a fair comparison of appendix M1 and SPE07 would involve a study where the test conditions of each are swapped and the test results compared. (AHRI, No. 14 at p. 10) AHRI added that measurement uncertainties associated with both procedures should be accounted for in the comparison as well. (*Id.*)

(7) Communicating and Non-Communicating Variable Speed Systems

Controls used with CAC/HPs may transfer information between system components (*i.e.,* communicating systems), or they may use more conventional low-voltage on-off signals to indicate ''calls'' for space conditioning and/or consumer selection of fan settings (*i.e.,* non-communicating). Communicating systems are defined as those that communicate the difference between space temperature and space setpoint temperature to the control that sets compressor speed and provides a signal to the indoor fan to set fan speed appropriate for compressor staging and air volume rate. 87 FR 16830, 16837. In the January 2023 RFI, DOE requested test data that could potentially show how the performance of communicating and non-communicating variable speed CAC/HPs compares when tested using load-based methods, and how do load-based methods address modulation of compressor speed for systems equipped with non-communicating controls. 88 FR 4091, 4100.

In response, Daikin, Rheem, AHRI, and NYSERDA commented that they are not aware of any test or field data comparing the performance of communicating and non-communicating systems when tested using load-based methods. (Daikin, No. 16 at p. 6; Rheem, No. 12 at p. 5; AHRI, No. 14 at pp. 10–11; NYSERDA, No. 9 at p. 10)

Daikin commented that load-based test methods would incentivize manufacturers to develop control schemes that optimize performance in the test lab rather than in the field. (Daikin, No. 16 at p. 6) Daikin further stated that the definition adopted by DOE in the October 2022 Final Rule [38] for Variable Speed Coil-Only systems was too restrictive and will limit technology and progress. (*Id.*)

Rheem commented that even for non-communicating systems, operating parameters of the refrigeration cycle are affected by the heat sink temperatures and heat source. Rheem listed suction pressure, liquid line pressure, return gas temperature, and liquid line temperature as the parameters, and cited a research paper [39] that outlined a variable system controlled by refrigerant superheat. (Rheem, No. 12 at p. 5)

NYSERDA commented that a non-communicating thermostat would not typically allow the variable speed system to modulate, and the system will simply cycle on and off like a single-speed system. (NYSERDA, No. 9 at p. 10) NYSERDA cited a research paper indicating that for low-load conditions, variable speed units suffer more from cycling losses in comparison to single-stage and two-stage systems. (*Id.*)

(8) Load-Based Testing for Single-Stage and Two-Stage Systems

In the January 2023 RFI, DOE requested comment on whether there

www.techstreet.com/standards/lv-22-c025-comparison-of-residential-heat-pump-heating-seasonal-performance-based-on-load-based-and-steady-state-testing-methodologies?product_id=2505150.

[35] Heat Pump and Air Conditioner Efficiency Ratings: Why Metrics Matter. Available at *neea.org/resources/heat-pump-and-air-conditioner-efficiency-ratings-why-metrics-matter.*

EXP07:19 Load-Based and Climate-Specific Testing and Rating Procedures for Heat Pumps and Air Conditioners. Available at *neea.org/resources/exp0719-load-based-and-climate-specific-testing-and-rating-procedures-for-heat-pumps-and-air-conditioners.*

CSA EXP07: Ongoing Progress, Lessons Learned, and Future Work in Load-based Testing of Residential Heat Pumps. Available at *neea.org/resources/csa-exp07-ongoing-progress-lessons-learned-and-future-work-in-load-based-testing-of-residential-heat-pumps.*

EXP07 Value Engineering Memo and PowerPoint. Available at *neea.org/resources/exp07-value-engineering-memo-and-powerpoint.*

[36] The NEEP Heat Pump Rating Representativeness Project. Available at *neep.org/sites/default/files/media-files/hp_representativeness_research_project-rfp_7.7.21.pdf.*

[37] In one of its comments, NYSERDA referred to the contents in Table II–1, which outlines the applicability of the load-based methods to equipment types (ducted or non-ducted), and the capacity measurement procedure (calorimetric room or air enthalpy method). (NYSERDA, No. 9 at p. 9) NYSERDA commented that DOE did not point out that SPE07 applies to ducted equipment, and the ENERGY STAR CCHP CVP applies to non-ducted equipment. DOE would like to point out that it did, in fact, indicate in the table that SPE07 and the ENERGY STAR CCHP CVP are applicable to ducted and non-ducted equipment, respectively.

[38] Section 1.2 of appendix M1 defines ''Communicating Variable Speed Coil-Only Central Air Conditioner or Heat Pump'' as follows: Variable speed Communicating Coil-Only Central Air Conditioner or Heat Pump means a variable speed compressor system having a coil-only indoor unit that is installed with a control system that (a) communicates the difference in space temperature and space setpoint temperature (not a setpoint value inferred from on/off thermostat signals) to the control that sets compressor speed; (b) provides a signal to the indoor fan to set fan speed appropriate for compressor staging and air volume rate; and (c) has installation instructions indicating that the required control system meeting both (a) and (b) must be installed.

[39] Yang, D. S., Lee, G., Kim, M. S., Cho, Y. M., Hwang, Y. J., & Chung, B. Y. (2004). *A study on the capacity control of a variable speed vapor compression system using superheat information at compressor discharge.* In *10th International Refrigeration and Air Conditioning Conference at Purdue, July 12–15, 2004.* Purdue University Libraries, West Lafayette, IN. Available at *docs.lib.purdue.edu/iracc/689/.*

are aspects of single- and two-stage system operation that are not adequately captured by appendix M1, and if load-based testing should be applicable to them. 88 FR 4091, 4101. DOE also requested comment on whether the current cyclic tests in appendix M1 adequately capture cyclic losses associated with cycling of compressors when unit capacity exceeds building load. (*Id.*)

In response, the Joint Advocates commented that even though load-based testing is best suited to accurately capture part-load operation of variable speed systems, it may be beneficial to apply it to single-stage and two-stage systems. (Joint Advocates, No. 8 at p. 2) In contrast, Carrier commented that appendix M1 captures the performance of single- and two-stage systems adequately, and the application of load-based testing to these systems will not provide any value. (Carrier, No. 5 at p. 5) Daikin commented that if fixed-speed testing (currently in appendix M1) is used for single-stage and two-stage products and load-based testing is used for variable speed products, then it will not be possible to compare these products on an equivalant basis. (Daikin, No. 16 at p. 6) Similarly, Rheem pointed out that load-based testing is mainly appropriate for variable speed products, and its suitability for single-stage and two-stage systems is questionable. (Rheem, No. 12 at p. 5) AHRI commented that any test procedure needs to compare different equipment classes on an equal basis. (AHRI, No. 14 at p. 11)

Regarding cyclic losses, the Joint Advocates commented that appendix M1 fails to properly account for the cycling performance of units. (Joint Advocates, No. 8 at p. 2) The Joint Advocates referred to the current method of calculating the cyclic degradation coefficient in appendix M1 [40] and cited a research paper [41] to highlight the issues in this calculation methodology. (*Id.*) Daikin pointed out the unsuitability of load-based tests for capturing cyclic losses, by stating that the cyclic tests in appendix M1 are executed with dry indoor coils since it is not easy to measure briskly changing moisture content during these tests. (Daikin, No. 16 at p. 6) Daikin added that for load-based cyclic tests, the coils will get wet, which will lead to concerns with the repeatability and reproducibility of capturing cyclic losses using load-based methods. (*Id.*)

(9) Other Factors Affecting System Energy Use

In the January 2023 RFI, DOE requested comment on how load-based testing could be used to capture other parameters that affect energy use of CAC/HPs, particularly, but not limited to, defrost systems, operation of electric resistance heat, operation of fans during the shoulder season, and operation of crankcase heaters during off-mode hours. 88 FR 4091, 4101.

In response, Rheem commented that most power consumption is accounted for in the off-mode test procedure,[42] except fan-only operation, which may be difficult to capture in a load-based test since outside air is not introduced during operation. (Rheem, No. 12 at p. 5) AHRI commented that incorporation of the parameters and aspects mentioned by DOE would result in the need for new energy efficiency descriptors. (AHRI, No. 14 at p. 11) NYSERDA recommended that DOE adopt an average space heating capacity adjustment using a defrost degradation coefficient consistent with the provisions of a test procedure term sheet issued by the Appliance Standards and Rulemaking Federal Advisory Committee Commercial Unitary Air Conditioner and Heat Pump Working Group on December 15, 2022 (''2022 ASRAC CUAC and CUHP WG TP term sheet'').[43] (NYSERDA, No. 9 at pp. 10–11) NYSERDA commented that the cyclic defrost tests in appendix M1 (at outdoor temperature of 35 °F) could still be applicable for evaluating the maximum defrost degradation. (*Id.*)

(c) Commenter Conclusions Regarding Load-Based Testing

In general, almost all commenters pointed toward several issues with load-based testing that make it infeasible for adoption as a regulatory test method at this time. Carrier commented that it is strongly opposed to DOE adopting any of the load-based testing procedures described in the January 2023 RFI since current research on these methods needs to be finalized before DOE incorporates them into the test procedure. (Carrier, No. 5 at p. 2) Daikin pointed out that while load-based testing may be appropriate when used as a CVP (similar to how it is used for VRF products in AHRI 1230–2021: 2021 Standard for Performance Rating of Variable Refrigerant Flow Multi-Split Air-Conditioning and Heat Pump Equipment (''AHRI 1230–2021'')),[44] it is not suitable for evaluating unit efficiency and capacity. (Daikin, No. 16 at p. 1) Daikin encouraged DOE to make modifications to the existing appendix M1 and adopt a CVP in appendix M1 that is similar to the VRF CVP, but not to adopt load-based testing as the primary regulatory test method. (*Id.* at pp. 1–2) Similary, AHRI commented that although it will support the improvement of load-based testing as an academic pursuit, load-based testing has not yet developed sufficiently such that it may be used for regulatory purposes. (AHRI, No. 14 at p. 7) AHRI further commented it expects DOE to carefully evaluate all the information manufacturers have to report for certification of their products and also evaluate the burden for this reporting and testing if planning to adopt load-based testing. (*Id.*) NEEA stated that although it has published several articles that question the rank order performance ratings evaluated from fixed-speed testing, there is currently no clear evidence that exhibits the advantages of load-based testing. (NEEA, No. 13 at p. 1) NYSERDA commented that regarding the adoption of load-based methods for regulatory purposes, DOE should account for products such as coil-only systems, split system ACs or HPs with coil blowers, and multi-split products.[45] (NYSERDA, No. 9 at p. 6) NYSERDA further commented that there is still more work that needs to be done in order to make load-based testing suitable for DOE regulatory purposes. (*Id.*) Finally,

[40] Sections 3.5 and 3.8 of appendix M1 contain provisions for conducting optional cooling and heating cyclic tests. These cyclic tests are used to determine the Coefficient of Degradation (''CD''), which is incorporated into the calculation of SEER2 and HSPF2, to account for any compressor cycling losses. If the optional cyclic tests are not conducted, appendix M1 requires use of the default CD value of 0.25. However, for the majority of single- and two-stage systems, a lower CD can be achieved when completing the optional cyclic tests, which results in higher SEER2 and HSPF2.

[41] Dhumane, Rohit; Qiu, Tianyue; Ling, Jiazhen; Aute, Vikrant Chandramohan; Hwang, Yunho; Radermacher, Reinhard; Kirkwood, Allen Chad; and Esformes, Jack, ''Evaluating the Impact of the Measurement Setup on Cyclic Degradation Coefficient of Air Conditioning Systems'' (2018). International Refrigeration and Air Conditioning Conference. Paper 2012. Available at *docs.lib.purdue.edu/iracc/2012*.

[42] Section 3.13 of appendix M1 outlines the procedure to determine off-mode average power ratings.

[43] On July 21, 2022, ASRAC chartered the CUAC and CUHP Working Group to negotiate term sheets on the test procedure and energy conservation standards for CUACs and CUHPs. On December 15, 2022, the Working Group completed a term sheet for the test procedure, which is available at *www.regulations.gov/document/EERE-2022-BT-STD-0015-0065*.

[44] *See www.ahrinet.org/system/files/2023-06/AHRI_Standard_1230-2021.pdf*.

[45] DOE believes that NYSERDA made this comment owing to the fact that SPE07 does not explicitly state that it is applicable to these product types.

NYSERDA stated that although it supports a feasible and representative load-based approach, developing a procedure could be challenging. (*Id.* at p. 4) The CA IOUs encouraged DOE to collaborate with stakeholders to move to a test procedure that requires units to operate under native controls, but recognized that an industry-wide transition to load-based testing will be time consuming and cost intensive. (CA IOUs, No. 10 at pp. 1–2) The Joint Advocates commented that load-based testing methodologies would provide better information on the field operation of a CAC/HP, in comparison to the fixed-speed tests currently in appendix M1. (Joint Advocates, No. 8 at pp. 1–2) The Joint Advocates referred to how the native controls testing in DOE's Cold Climate Heat Pump Technology Challenge (''DOE CCHP Tech Challenge'') [46] was informed by the results of the steady-state regulatory tests,[47] and suggested that DOE could adopt a similar provision for both cooling and heating tests, in its amended load-based test procedure. (*Id.*)

Instead of wholesale adoption of a load-based method, comments received on the January 2023 RFI pointed toward consensus preference for a limited form of load-based testing to verify steady-state regulatory test performance under native controls (*i.e.,* a CVP). Samsung, Lennox, AHRI, NYSERDA, NEEA, and Rheem all encouraged DOE to adopt a CVP that would ensure settings used during steady state tests are representative of those during native controls operation. (Samsung, No. 11 at pp. 1–2; Lennox, No. 6 at p. 3; AHRI, No. 14 at p. 7; NYSERDA, No. 9 at p. 5; NEEA, No. 13 at p. 3; Rheem, No. 12 at p. 3) Specifically, Lennox stated that while steady state testing currently used in appendix M1 should continue to be used, a CVP can be used to validate the settings used to test variable capacity systems. (Lennox, No. 6 at p. 3) AHRI commented that use of a CVP would be more repeatable and less burdensome than using load-based testing for direct measurement of performance, adding that CVPs have been used for other product categories and may need some adapatation for application to CAC/HPs. (AHRI, No. 14 at p. 9) Additionally, AHRI referred to a study it co-sponsored with NEEA to collect representative field data, which was expected to conclude at the end of winter 2022/2023. (*Id.* at p. 9) NYSERDA described the CVP used in AHRI 1230–2021 for VRFs and recommended that DOE adopt something similar to it. (NYSERDA, No. 9 at p. 5) NYSERDA further recommended that DOE adopt the CVP outlined in ENERGY STAR Spec V6.1 for the low ambient heating steady-state tests in appendix M1, namely $H3_2$ and $H4_2$. (*Id.* at pp. 5–6) NYSERDA referred to how the wet bulb test conditon in the H4 heating test had increased from 3 °F to 4 °F, which would decrease test burden for labs if they conduct a load-based CVP outlined in ENERGY STAR Spec V6.1. (*Id.*) NYSERDA further encouraged DOE to adopt a ''budget'' method to account for variability in critical parameters during a CVP, and recommended incorporation of a CVP for validating the $H1_1$ (heating minimum) test, and also a minimum-speed CVP at outdoor dry bulb temperature of 17 °F.[48] (*Id.*) NYSERDA commented that performance of units at part-load at milder temperatures has a pronounced impact on the overall seasonal energy efficiency, especially when considering the intersection of low-speed loads beween 17 °F and 47 °F, highlighting that this impact was not fully considered in implementation of the ''Min/Mild'' CVP in the specifications of the DOE CCHP Tech Challenge. (*Id.* at p. 6) NEEA referred to the two types of CVPs as descibed in section III.F.1.b. and commented the results of a study it performed called into question whether a CVP can truly capture the impact of native controls on unit performance.[49] (*Id.* at pp. 3–6) Hence, NEEA commented that DOE needs additional test data to make any claims that CVP testing fully addresses the impact of native control logic on unit performance. *Id.* NEEA pointed to the representativeness study [50] being conducted by NEEP on three ducted and three non-ducted heat pumps, tested using AHRI 210/240 and SPE07, and stated that this study could potentially indicate what elements of a CVP are critical to include in a revised appendix M1, and also inform other issues raised by DOE in the RFI, namely the repeatability, reproducibility, and test burden of load-based methods when compared to fixed-speed testing. (*Id.* at pp. 2–3)

To summarize, comments from the January 2023 RFI indicated that stakeholders preferred a CVP for validating the performance of variable capacity systems, rather than adopting a load-based testing method for regulatory purposes.

(d) DOE's Conclusion and Approach

As mentioned previously, AHRI and other relevant stakeholders, including DOE, participated in the development of revised AHRI test standards to address the issues raised in the January 2023 RFI. In particular, the issues outlined in the aforementioned comments in regard to the representativeness of fixed-speed testing for variable speed systems were discussed in detail and consensus was developed on a CVP approach. Based on review of the stakeholder comments received in response to the January 2023 RFI, specifically that it has not yet been conclusively demonstrated that such methods have sufficient repeatability and reproducibility to be the basis of direct measurement of system performance, DOE has tentatively concluded that use for direct measurement of performance for regulatory purposes would not be suitable at this time. However, DOE also tentatively concludes that a CVP would be necessary to ensure that fixed-speed settings of variable speed systems would be achieved using native (unfixed) control. Thus, DOE proposes to adopt the CVP outlined in AHRI 210/240–202X Draft and AHRI 1600–202X Draft through incorporation by reference. The next section discusses the aforementioned CVP approach.

(e) CVP Proposal

Appendix I of the AHRI 210/240–202X Draft and AHRI 1600–202X Draft includes a CVP to verify variable capacity system operation. The CVP is intended to validate whether override of modulating components in regulatory tests is consistent with native control operation. The CVP verifies: (1) compliance with the variable capacity compressor system definition; and (2) consistency of fixed-position settings for the compressor and indoor fan used in steady-state regulatory tests with native control operation.

The CVP in appendix I includes a set of three cooling tests conducted in

[46] On May 19, 2021, DOE, in conjunction with EPA and NRCan, announced the DOE CCHP Tech Challenge as part of the Energy, Emissions and Equity (''E3'') Initiative. The specification of the DOE CCHP Tech Challenge is available at *www.energy.gov/sites/default/files/2021-10/bto-cchp-tech-challenge-spec-102521.pdf.*

[47] As an example, if a heating capacity of 18,000 Btu/h was measured during the $H1_1$ regulatory test, the native controls ''Min/Mild'' test would apply an equivalent 18,000 Btu/h cooling load to the indoor room's conditioning equipment.

[48] Currently, appendix M1 only has a full-speed heating test at an ambient outdoor temperature of 17 °F, *i.e.,* the $H3_2$ test.

[49] Bruce Harley, Mark Alatorre, Christopher Dymond, Gary Hamer, ''CSA EXP07: Ongoing Progress, Lessons Learned, and Future Work in Load-based Testing of Residential Heat Pumps'' (2022). Purdue University. Available at *docs.lib.purdue.edu/cgi/viewcontent.cgi?article=3455&context=iracc.*

[50] In its comment, NEEA pointed out that preliminary analysis and data from this study will be available probably by July 2023, but at the time of writing this NOPR, neither the analysis, nor the data, has become available.

series with intervening transition periods, including the full, intermediate, and minimum capacities. The CVP uses a modified VBL [51] approach to simulate space condition (temperature and humidity) response to system operation, as explained in section III.F.1.b.3 of this document. Similarly, the CVP also includes three or four heating tests conducted in series for CHPs—the fourth test is specified for those CHPs for which performance at 5 °F outdoor temperature is measured. Similar to the cooling tests, the heating tests have intervening transition periods between the full, intermediate, and minimum capacity test intervals.

For the three cooling tests, the indoor return air conditions are controlled by equations I1–I6 and paragraph I4.1.8 in AHRI 210/240–202X Draft and AHRI 1600–202X Draft—*i.e.,* the indoor return air wet bulb temperature is set at 67 °F, and the indoor return air dry bulb target varies near 80 °F based on the varying system capacity and calculated building load. The temperature setpoint of the control of the system being tested is set throughout the series of tests near 80 °F with some adjustment to account for control bias and offset. The outdoor dry bulb temperature is held constant at three different levels during the three cooling-mode tests, but is controlled to ramp down from higher to lower temperature as the cooling mode CVP transitions between the full load, intermediate load, and low load test intervals.

For the heating tests, the indoor return air conditions are controlled by equations I7–I13 in AHRI 210/240–202X Draft and AHRI 1600–202X Draft. The indoor return air dry bulb temperature varies near 70 °F based on the varying system capacity and calculated building load. The temperature setpoint of the control of the system being tested is set throughout the series of tests near 70 °F with some adjustment to account for control bias and offset. The outdoor dry bulb temperature is held constant at three or four different levels, but is controlled to ramp up from lower to higher temperature as the heating mode CVP transitions between the full load (at 5 °F if applicable and 17 °F outdoor dry bulb temperature), intermediate load, and low load test intervals.

As noted, part of the CVP (the intermediate-load test) determines compliance with the variable-capacity compressor system definition. AHRI 210/240–202X Draft and AHRI 1600–202X Draft define variable capacity compressor systems as:

Variable capacity compressor system means an air conditioner or heat pump that has either (a) a compressor that uses a variable speed drive or inverter to vary the compressor speed by four or more speeds in each mode of operation (*i.e.,* cooling/heating), or (b) a digital compressor that mechanically modulates output using a duty cycle; and which controls the system by monitoring system operation and automatically modulating the compressor output, indoor air flow and other system parameters as required in order to maintain the indoor room temperature.

To determine compliance with the definition, the CVP results obtained from the intermediate load interval is evaluated based on section I4.3.1 of appendix I in in AHRI 210/240–202X Draft, which requires that the standard deviation of the system power does not exceed 20 percent of the mean system power. For a system that does not comply with this compressor power (or outdoor unit power) requirement, and cycles between off and a single stage or capacity level (+/ − 15 percent), the system is classified as a variable capacity certified, single capacity system. If this occurs for just one of the operating modes (heating or cooling) for a heat pump, the system is classified as variable capacity certified, single capacity for both modes. Additionally, a system that does not comply with the compressor power (or outdoor unit power) requirement is not classified as Variable Capacity Certified, Single-Capacity, and cycles between more than one stage or capacity level (+/ − 15 percent) is classified as a Variable Capacity Certified, Two-Capacity System. Again, this designation applies for both modes for a heat pump, even if the operation meets this description for one of the modes. These terms are defined in AHRI 210/240–202X Draft and AHRI 1600–202X Draft as:

Variable Capacity Certified, Single Capacity System means a system that is certified as a variable capacity system but demonstrates Single-Capacity System behavior during the Variable Capacity Determination CVP in appendix I.

Variable Capacity Certified, Two Capacity System means a system that is certified as a variable capacity system, but demonstrates Two-Capacity System behavior during the Variable Capacity Determination CVP in appendix I.

Use of the Intermediate Load CVP test and its determination of compliance with the variable speed system definition in DOE enforcement testing is discussed in section III.K.2 of this document.

The full-load and low-load intervals of the CVP determine if the fixed-speed settings for the compressor and indoor fan used during the regulatory test are consistent with those that occur when the unit is allowed to modulate under native controls, as it maintains the indoor room dry bulb temperature. During the cooling mode CVP,[52] the indoor return air wet bulb temperature is maintained at 67.0 °F, but the updated target indoor dry-bulb temperature setpoint for the indoor room reconditioning system, $RAT(t + \Delta t)$, is updated based on equations I4–I6 of AHRI 210/240–202X Draft and AHRI 1600–202X Draft, as shown below:

$$RAT(t+\Delta t) = RAT(t) + \frac{\Delta t[VLs(T_J) - \dot{Q_S}]}{C},$$

Where,

$RAT(t)$ = the current indoor dry-bulb temperature setpoint for the indoor room reconditioning system

$\dot{Q}_s$ = the net sensible cooling capacity provided by the unit under test in the current time step, as determined by air-side measurements (*see* note below)

Δt = the time interval for updating the indoor room reconditioning system controller setpoint, in h

C = the simulated thermal capacitance of the building interior, in units of Btu/°F, given by

$$C = \frac{SHR_{A,full} * \dot{Q}_c(95)}{24}$$

$VLs(T_j)$ = the sensible cooling portion of the modified VBL for target outdoor ambient dry-bulb temperature for each interval.

The magnitude of $VLs(T_j)$ is directly proportional to the certified cooling

[51] The modified VBL in the CVP differs from the VBL in SPE07. For the modified VBL, the building load used in the equations does not depend on the indoor temperature and is a fixed function of target indoor and outdoor temperatures.

[52] For brevity, only cooling mode is explained in the NOPR, to illustrate the 2nd part of the CVP.

capacity at 67 °F outdoor ambient-dry bulb temperature—*i.e.,* the F_{low} test, and the target SHR from the F_{low} regulatory tests, as illustrated in equations I1 and I3 of AHRI 210/240–202X Draft and AHRI 1600–202X Draft. Thus, this illustrates that the modulation of the compressor speed setting and indoor air flow rate is verified against those used in the regulatory tests, as the unit tries to maintain the indoor dry-bulb temperature.

DOE proposes that load-based testing will be not part of the test procedure required for each test for any CAC/HP products. DOE acknowledges that the CVP approach outlined in appendix I of the relevant AHRI drafts represents industry consensus regarding the verification of compliance of systems with the variable capacity system definition, and to verify the consistency of fixed-speed settings of compressor and indoor fan with native control operation as part of enforcement. DOE considers that this CVP approach will provide a more representative test procedure for variable speed systems operating in the field, because it provides a tool to verify that the compressor speed settings and indoor air fan settings used in regulatory tests are representative of native-control operation as the unit operates to maintain the thermostat setpoint, *i.e.,* indoor dry-bulb temperature. Therefore, DOE is proposing to incorporate by reference appendix I of the AHRI 210/240–202X Draft to support enforcement associated with testing conducted in accordance with appendix M1, and to incorporate by reference appendix I of the AHRI 1600–202X Draft to support enforcement associated with testing conducted in accordance with appendix M2. This is discussed in more detail in section III.K.2 of this document.

2. Low-Temperature Heating Performance

In the January 2023 RFI, DOE requested comment on several issues regarding the foundational work needed to improve the appendix M1 test procedure to better account for CAC/HP performance in cold climates, as recommended by NYSERDA during the previous rulemaking cycle that culminated in the October 2022 Final Rule. 88 FR 4091, 4103. In response to the low-temperature heating performance issues raised in the January 2023 RFI (*i.e.,* whether to make the H4 heating tests mandatory, whether the heating load line should be based on heating or cooling capacity, and methods of heat pump sizing), DOE received several comments regarding the establishment of a clear definition for a CCHP as well as potential ways of reporting performance for CCHPs. These aforementioned topics are detailed in separate sections below.

(a) CCHP Definition

In response to the January 2023 RFI, several stakeholders commented in support of establishing a definition for products specifically engineered to provide comfort heating at low ambient conditions (*i.e.,* CCHPs). Daikin recommended that DOE work with stakeholders to establish a clear definition for CCHPs, whether as a separate product class or an optional set of recognition criteria. (Daikin, No. 16 at p. 9) Similarly, AHRI commented in support of a uniform definition for products specifically engineered to provide comfort heating at low ambient conditions. (AHRI, No. 14 at pp. 2–3) AHRI commented that engagement from all stakeholders would be necessary to overcome the shortcomings of previous efforts to develop a definition for CCHPs. (*Id.*)

Additionally, in forming a DOE definition for CCHPs, AHRI requested it be acknowledged that (1) not all U.S. consumers would benefit from higher-tech CCHPs, and (2) the topography of the United States makes it difficult to assign regions that would correlate heating degree days in the same way as is done for split-system air conditioners, as shown by Figure 1 [53] of AHRI's response to the January 2023 RFI. (AHRI, No. 14 at p. 3) Referring to Figure 1, AHRI commented that it is easy to see the cooling degree day division between the North and South, as in effect today, and that heating degree days, on the other hand, meander and are very closely tied to elevation and longitude (to some extent). (*Id.*)

As previously mentioned, AHRI and other stakeholders, including DOE, discussed several issues raised in the January 2023 RFI when considering updated versions of industry standards, including the topic of a clear definition for CCHPs. DOE notes that AHRI 210/240–202X Draft and AHRI 1600–202X Draft both include a new definition for CCHP as shown below:

Cold climate heat pump means a heat pump for which both low-temperature compressor cut-out and cut-in temperatures are specified to be less than 5 °F and for which capacity for the $H4_{full}$ test (at 5 ^{0}F) is certified to be at least 70 percent of the capacity for the nominal full capacity test conducted at 47 ^{0}F ($H1_{Full}$ or $H1_{Nom}$).

DOE surmises that the CCHP definition provided in the relevant AHRI drafts represents industry consensus regarding a uniform definition for products specifically engineered to provide comfort heating at low ambient conditions. DOE has also tentatively determined that the definition includes the relevant criteria to characterize CCHP performance, specifically low-temperature cut-out and cut-in temperature settings to allow operation down to at least 5 °F ambient temperature, and maintenance of heating capacity at low temperatures. Therefore, DOE is proposing to incorporate by reference the definition of a cold climate heat pump provided in the AHRI 210/240–202X and AHRI 1600–202X Drafts, at appendix M1 and appendix M2, respectively.

(b) Mandatory H4 Heating Tests for CCHPs

While the H4 heating tests provide meaningful information and more representative ratings for products designed specifically for low temperature operation, in the January 2023 RFI, DOE noted that the current appendix M1 test procedure includes H4 heating tests as optional tests, as they may not be appropriate for all HPs. 88 FR 4091, 4103. Currently, appendix M1 allows the performance at 5 °F to be extrapolated based on tests conducted at 17 °F and 47 °F (*i.e.,* using the $H3_2$ and $H1_2$ tests, respectively) for HPs that are not tested at the H4 heating condition.

As such, in the January 2023 RFI, DOE requested comment on whether it would be appropriate to make the H4, $H4_2$, or $H4_3$ heating tests in appendix M1 mandatory for either all or a subset of HPs (*e.g.,* CCHPs) in order to produce more representative ratings that account for system performance at 5 °F. 88 FR 4091, 4103. In the case of mandating the H4 heating tests for only a subset of HPs, DOE requested information on what characteristics would represent a clear delineation to distinguish such models from others. (*Id.*) DOE also requested information on the prevalence of test chambers capable of testing CHPs at an outdoor ambient temperature of 5 °F. (*Id.*)

In response, AHRI and Daikin recommended that the H4 tests be mandated only for variable speed HPs for which the compressor speed at the H4 condition was different from that at the H1 and H3 condition. (AHRI, No. 14 at p. 13; Daikin, No. 16 at p. 9) Daikin

[53] Figure 1 of AHRI's response to the January 2023 RFI shows average annual cooling and heating degree days in the contiguous United States from 1901–2000, using National Centers for Environmental Information (''NCEI'') data compiled by the National Oceanic and Atmospheric Administration (''NOAA''). (AHRI, No. 14 at p. 3) A degree day is equivalent to one day with an average temperature that is one degree above or below 65 °F.

asserted that it does not make sense to require the H4 tests for any HP that does not change speed, because, for single- and two-stage HPs, performance at 5 °F can be extrapolated based on existing test data since compressor performance is linear for those products. (Daikin, No. 16 at p. 9) Daikin clarified that the mandatory H4 tests would be applicable even for a variable speed HP where the manufacturer is targeting the southern United States as a market. (*Id.*)

Like AHRI and Daikin, Rheem commented against mandating the H4 tests for single- and two-stage equipment; however, Rheem neither supported nor opposed mandating the H4 tests for variable speed systems. (Rheem, No. 12 at p. 7) Rheem noted that the current test procedure in appendix M1 allows linear extrapolation of heat pump performance at outdoor temperatures colder than 17 °F using equations 4.2.1–4 and 4.2.1–5 for HPs having a single-speed compressor, and using equations 4.2.2–3 and 4.2.2–4 for HPs having a two-capacity compressor. (*Id.*) As such, Rheem commented that the test procedure in appendix M1 reliably indicates heat pump performance in cold climates for single- and two-stage equipment. (*Id.*) However, for variable speed systems, Rheem acknowledged that, in addition to compressor speed, indoor and outdoor airflow rates may change, which may bring the accuracy of linear extrapolation into question for these systems. (*Id.*)

Lennox commented against the idea of making the H4 tests mandatory for any HPs, contending that consumer needs in many areas of the United States with milder climates do not need the capability of a CCHP and, thus, should not require the additional test burden associated with mandatory H4 tests. (Lennox, No. 6 at p. 4)

NEEA recommended making the H4 heating tests mandatory for all HPs, but not required within the test metric, contending that this would result in a more representative assessment of cold climate efficiency and capacity across all HPs. (NEEA, No. 13 at pp. 7–8) Further, NEEA commented that in conversations with industry representatives, NEEA has received indications that many manufacturers already have test chambers that can test down to 5 °F, suggesting that the testing infrastructure is already in place to implement a mandatory requirement for the H4 heating tests. (*Id.*)

NEEA also recommended that for units required to test at part-load conditions (*e.g.,* CCHPs), DOE require reporting unit COP at part load conditions. (NEEA, No. 13 at p. 7) Specifically, NEEA recommended that DOE require the reporting of COP at F_{Low} (at 67 °F) and $H1_{Low}$ (at 47 °F) for units that are required to test at those conditions. (*Id.*) NEEA commented that, by requiring manufacturers to report this data in a consistent format, contractors will be able to make better-informed choices about equipment that works in their climate, and utility companies will know which heat pumps to recommend (*i.e.,* incentivize) to their customers. (*Id.*) NEEA pointed to DOE's CCHP Tech Challenge specifications as an example of the kind of information that consumers and utilities need in order to make informed decisions for their desired region and application. (*Id.*)

NYSERDA encouraged DOE to make $H4_2$ tests mandatory, but only for United States North climate regions, at air-entering outdoor unit temperatures of 5 °F dry bulb and 4 °F (max) wet bulb. (NYSERDA, No. 9 at p. 4) NYSERDA explained that a precedence for mandatory $H4_2$ tests was recently codified in Canada's *Regulations Amending the Energy Efficiency Regulations, 2016 (Amendment 17),* published in the Canada Gazette, Part II, on December 7, 2022.[54] (*Id.*) NYSERDA noted that mandatory reporting requirements to National Resources Canada (''NRCan'') as of January 1, 2023, are as follows: (a) a Region V HSPF2; (b) information that indicates whether the results of the appendix M1 H4 test, if conducted, were included in the calculation of the Region V HSPF2; (c) heating capacity at 5 °F if the H4 test was conducted; and (d) COP at 5 °F if the H4 test was conducted. (*Id.*) Further, NYSERDA noted that, in Canada, HPs manufactured on or after January 1, 2025, must be tested at the H4 test conditions prescribed in appendix M1, and that mandatory reporting requirements to NRCan for the H4 test conditions include heating capacity at 5 °F and COP at 5 °F. (*Id.*) More broadly, NYSERDA recommended that DOE should study more carefully whether the incentives to conduct the optional $H4_2$ tests on good-performing cold climate equipment (because it would increase the HSPF2 rating, particularly in region V) are enough to ensure that most manufacturers would conduct the test to demonstrate that benefit. (*Id.*)

As previously mentioned, AHRI and other stakeholders, including DOE, discussed issues raised in the January 2023 RFI, including the topic of mandatory H4 heating tests for either all or a subset of HPs, when developing updated industry standards in AHRI 210/240–202X Draft and AHRI 1600–202X Draft. DOE notes that these draft industry standards include a footnote to Table 7 (*i.e.,* the required tests table), applicable to all product types, requiring the $H4_{full}$ heating test for all products that meet the definition of a CCHP. DOE surmises that this new mandate for all products certified as a CCHP in the relevant AHRI drafts represents industry consensus regarding whether it would be appropriate to make the H4 heating tests mandatory for either all or a subset of HPs. DOE has tentatively determined that the H4 heating tests are representative of CCHP operation. Therefore, in addition to its proposal to incorporate the CCHP definition as discussed in section III.E.2.a of this document, DOE is proposing to incorporate by reference the mandate for products certified as CCHP to conduct the H4 heating tests (either the H4, $H4_2$, or $H4_3$ heating test, as applicable) provided in the AHRI 210/240–202X Draft and AHRI 1600–202X Draft, at appendix M1 and appendix M2, respectively.

(c) Heating Load Line and Sizing for CCHPs

In a supplemental notice of proposed rulemaking (''SNOPR'') regarding CAC/HP test procedures published on August 24, 2016 (''August 2016 SNOPR''), DOE noted that most heat pump units in the field are sized based on cooling capacity as opposed to heat pump capacity, consistent with the Air Conditioning Contractors of America (''ACCA'') Manual S provisions. 81 FR 58163, 58188. Subsequently, in the January 2017 Final Rule, DOE revised appendix M1 such that the determination of the heating load line was based on cooling capacity rather than heating capacity. 82 FR 1426, 1453–1454. In the January 2023 RFI, DOE explained that part of the motivation for this change was that the previous approach of heating load line determination based on the nominal heating capacity (''$H1_N$ capacity'') provided little incentive to design for good heat pump performance, since low $H1_N$ capacity resulted in a low load line and generally better HSPF2. 88 FR 4091, 4103. DOE explained that sizing based on cooling capacity is consistent with trends for sales distributions of heat pumps, which have had greater adoption in milder climates than cold climates.[55] (*Id.*) However, DOE also

[54] *See canadagazette.gc.ca/rp-pr/p2/2022/2022-12-21/html/sor-dors265-eng.html.*

[55] Residential Energy Consumption Survey (''RECS'') 2020 data shows that electric heat pumps represent 29 percent of primary space heating equipment in homes in the South region, which is a higher number as compared to the 14 percent for

Continued

expressed awareness that NRCan has proposed alternatives for sizing CAC/HPs, in its ''Air Source Heat Pump Sizing and Selection Guide,'' [56] which provides four different approaches with varying emphasis on heating vs. cooling, ranging from sizing based on cooling to sizing such that the heat pump can meet the design heating load without need for resistance auxiliary heat. (*Id.)* In the January 2023 RFI, DOE acknowledged that in cold climates, sizing a heat pump for heating may be more appropriate than sizing for cooling. (*Id.*) Further, DOE acknowledged that accurate information regarding heat pump cold-weather performance is relevant for selection of the best heat pumps for cold climates. (*Id.*) Nevertheless, DOE found it unclear how a test procedure using a heating load line based on heating performance would incentivize good heating performance, particularly if it is based on heating performance at 47 °F, which is not a heating design temperature, and noted that this is the same issue that led DOE to move to the cooling-capacity-based heating load line in appendix M1 in the January 2017 Final Rule.[57] (*Id.*) As a result, in the January 2023 RFI, DOE requested comment on whether the test procedure for CCHPs should use a heating load line based on heating performance, and how such an approach could be implemented such that it does not weaken the incentive for good cold-temperature heating performance.

In response, NYSERDA commented that sizing for cooling mode in climates where HPs will increasingly be relied upon to provide full home heat is not an appropriate approach to ensure that the right equipment is sized and selected, and suggested that a regional approach to HSPF2 ratings should be considered for CCHPs to allow for the prioritization of design heating performance. (NYSERDA, No. 9 at p. 2) NYSERDA commented in support of prioritizing sizing based on design heating loads at design temperatures as low as −4 °F, specifically pointing to the NRCan ''Air Source Heat Pump Sizing and Selection Guide'' mentioned previously. (*Id.*) Citing the NEEP ''Guide to Sizing & Selecting Air-Source Heat Pumps in Cold Climates,'' [58] NYSERDA explained that installers are recommended to match system heating capacity (minus any reliance on auxiliary heat) at design temperatures within 100–115 percent of the estimated heating load. (*Id.*) Further, NYSERDA commented that in partnership with electric utilities in New York, NYSERDA has designed a tool for residential buildings capable of demonstrating that a CCHP sized for heating load may be considered to meet an alternate compliance method for the mechanical design requirements under the 2020 Energy Conservation Construction Code of New York State, which would typically apply to the International Energy Conservation Code (''IECC'') as well.[59] (*Id.*) NYSERDA noted that the tools and guidance around sizing for heating load were developed to ensure successful installations of CCHPs and grew out of market needs for this information. NYSERDA pointed to a DOE-sponsored market survey conducted of 156 ductless HP (single-split systems as defined in appendix M1) owners in Juneau, Alaska, that confirmed owners place emphasis on design heating loads while prioritizing climate, reducing fossil fuel usage, and lowering heating costs.[60] (*Id.*) The survey results showed that the ability to have air conditioning was ranked the lowest in terms of owners' priorities, that about 93 percent of homeowners expressed satisfaction with their decision to install ductless HPs, and that most respondents viewed ductless HPs as products that would entirely replace or significantly reduce the use of other heating sources.

Aside from its suggested design for heating in cold climates, NYSERDA commented that it would not support changing the heating load line equations in appendix M1. (NYSERDA, No. 9 at pp. 2–3) NYSERDA reasoned that revising the rating procedure to account for heating sizing in the building heating load line equation would essentially suppress the heating load seen by HPs and reduce or minimize the assumed use of auxiliary electric heat in the HSPF bin model. (*Id.*) NYSERDA commented that this would have the impact of overstating the performance of systems that have poor capacity in cold weather conditions, and would reduce (not emphasize) the differences in HSPF between those systems and others that have high capacity at low outdoor temperatures. (*Id.*)

The CA IOUs commented in support of NYSERDA's recommendation for assuming heat pump sizing based on the design heating load solely in heating-dominated regions. (CA IOUs, No. 10 at p. 4) Similarly, AHRI and Rheem both commented that they would support modifications to the test procedure to address the differences between the cooling and heating load profiles for colder climates. (AHRI, No. 14 at p. 13; Rheem, No. 12 at p. 7)

As previously mentioned, AHRI and other stakeholders, including DOE, discussed several issues raised in the January 2023 RFI, including the topic of the heating load line and sizing for CCHPs, when considering updated versions of industry standards. The information provided in the aforementioned comments was discussed in detail in the development of the AHRI 210/240–202X Draft and AHRI 1600–202X Draft, which include no exception for CCHPs to base the heating load line on heating performance rather than cooling performance. DOE surmises that the absence of such an exception in the relevant AHRI drafts represents industry consensus regarding whether the test procedure for CCHPs should use a heating load line based on heating performance, rather than cooling performance. Further, DOE has tentatively concluded that the aforementioned approach is appropriate for sizing of CCHPs and is consistent with DOE's position expressed in a prior rulemaking that the heating load line determination based on the nominal heating capacity (H1N capacity) provides little incentive to design for good heat pump performance, since low H1N capacity results in a low load line and generally better HSPF. (*See* 81 FR, 58164, 58186). This would hold true also if the heating load line was based on a different heating operating condition, *e.g.* capacity for 5 °F outdoor temperature, since poor performance at the test point would lower the heating load line. Therefore, DOE is proposing to incorporate no exception for CCHPs to base the heating load line on heating performance rather than cooling performance (*i.e.,* DOE proposes to retain the current size-for-cooling approach) at both appendix M1 and appendix M2.

US overall. *See www.eia.gov/consumption/residential/data/2020/hc/pdf/HC%206.8.pdf.*

[56] The ''Air Source Heat Pump Sizing and Selection Guide'' was written by NRCan in response to stakeholder requests for consistent guidance for sizing ASHPs according to the design heating or cooling load and intended use as well as identifying the appropriate system according to the installation and application. The four methods of sizing in the Guide are Options 4A (Emphasis on Cooling), 4B (Balanced Heating and Cooling), 4C (Emphasis on Heating) and 4D (Sized on Design Heating Load). The ''Air Source Heat Pump Sizing and Selection Guide'' is available at *publications.gc.ca/collections/collection_2021/rncan-nrcan/M154-138-2020-eng.pdf.*

[57] *See* 82 FR 1426, 1453–1459 of the January 2017 Final Rule.

[58] *See neep.org/sites/default/files/resources/ASHP%20Sizing%20%26%20Selecting%20-%208x11_edits.pdf.*

[59] *See cleanheat.ny.gov/contractor-resources/.*

[60] *See cchrc.org/media/2020-Juneau-DHP-Survey-Final1.pdf.*

(d) Cold Climate Heating Metric of Interest, COP_{peak}

Currently, the Federal energy conservation standards and certification, compliance, and enforcement provisions for CAC/HPs only require manufacturers to report the HSPF2 of HPs based on Region IV. However, DOE acknowledges that Region IV HSPF2 may not adequately represent the cold climate performance of such systems.

To better represent the heating performance of HPs in cold climates, in response to the January 2023 RFI, NYSERDA commented in support of the use and publication of Region V HSPF2 in addition to Region IV HSPF2, and of designating Region V HSPF2 as a relevant ''cold climate'' heating metric of interest. (NYSERDA, No. 9 at p. 3) Table 1 of NYSERDA's response summarizes the heating fractional bin hours for several U.S. cities in cold and very cold climate regions [61] and compares them to the current Region IV heating fractional bin hours presented in Table 20 of appendix M1. (*Id.*) NYSERDA stated that, since the heating fractional bin hours in Region V are present across all bins compared to Region IV, for cities located in climate zones designated as subarctic/arctic by the IECC, weather data suggest a Region V HSPF2 is more appropriate for all cold climate regions and shows focusing only on Region IV HSPF2 does not benefit consumers in colder climates. (*Id.*)

Similarly, AHRI commented in support of a test method for products specifically engineered to provide comfort heating at low ambient conditions. (AHRI, No. 14 at pp. 2–3) AHRI commented that engagement from all stakeholders would be necessary to overcome the shortcomings of previous efforts to develop testing methodologies for CCHPs. (*Id.*) Carrier also commented that all stakeholders could benefit from an update to appendix M1 that includes optional tests to improve the representativeness of products marketed as a CCHP. (Carrier, No. 5 at p. 1)

As previously mentioned, AHRI and other stakeholders, including DOE, discussed several issues raised in the January 2023 RFI when considering updated versions of industry standards, including the topic of test methods that accurately measure the cold climate heating performance of HPs. The information provided in the aforementioned comments was discussed in detail in the development of the AHRI 210/240–202X Draft and AHRI 1600–202X Draft, which add a new test method in appendix L to measure the heating performance of HPs at low ambient temperatures. Rather than designate Region V HSPF2 as the relevant ''cold climate'' heating metric of interest or requiring a separate test procedure for CCHPs, appendix L of the AHRI 210/240–202X and AHRI 1600–202X Drafts include the calculation steps for a new heating performance metric, the peak load coefficient of performance (''COP_{peak}''), intended to provide an indication of total heating efficiency as applied under peak heating load conditions. Specifically, COP_{peak} conveys the total energy consumed by both the HP and supplemental heat when meeting the building load at 5 °F, calculated using the equation below:

$$COP_{Peak} = \frac{BL(5)}{3.412 \cdot P_{Full}(5) + [BL(5) - \dot{q}_{Full}(5)]}$$

and BL(5) is the building load at 5 °F, is the electrical power consumption of the heat pump during the $H4_{Full}$ test, and $_{Full}$ is the space heating capacity of the heat pump during the $H4_{Full}$ test.

COP_{peak} provides the opportunity for manufacturers to make optional representations of their HPs, regardless of whether they are CCHPs, and is distinct from COP at the H4 testing conditions as it accounts for the additional resistance heat required to meet the building load under peak conditions. As such, COP_{peak} would be less than the tested COP at 5 °F but greater than 1, for any HP with COP greater than 1 at 5 °F.

DOE surmises that the inclusion of COP_{peak} in the relevant AHRI drafts represents industry consensus regarding improvements to representations of HP performance at low ambient temperatures. DOE has tentatively determined that inclusion of COP_{peak} would allow for representative characterizations of HP performance at low ambient temperatures. Therefore, DOE is proposing to incorporate by reference COP_{peak} as an optional representation for manufacturers hoping to advertise their HPs' peak load performance, as outlined in appendix L of the AHRI 210/240–202X and AHRI 1600–202X Drafts, at appendix M1 and appendix M2, respectively.

3. Cut-Out and Cut-In Temperature Certification

The calculation of HSPF2 in appendix M1 requires values for cut-out [62] and cut-in [63] temperatures (*see, e.g.,* equation 4.2.1–3 in section 4.2 of appendix M1). For CAC/HPs that do not include the cut-out and cut-in temperatures in their installation manuals, the manufacturer (or DOE, in the case of compliance testing) must provide the test lab with this information. In the January 2023 RFI, DOE explained that, based on lab testing, it has found manufacturers often use cut-out and cut-in temperatures in their HSPF2 calculations that are much lower than can be reasonably expected in the field—in some instances as low as −40 °F. 88 FR 4091, 4105. DOE expressed concern in this finding because of a review of product literature for scroll compressors with model numbers Copeland ZP*3KE and ZP*5KE R–410A (typically used in CAC/HPs) that shows the lowest refrigerant evaporating temperature of these systems is no lower than −10 °F.[64] (*Id.*)

In the January 2023 RFI, DOE also shared findings, in testing, that the ambient temperatures at which a unit's control cuts out and cuts in may significantly differ from the control's specified temperatures. 88 FR 4091, 4105. DOE acknowledged that this can be due to control component manufacturing variation. (*Id.*) However, DOE also explained that it can be due to sensors being located where

[61] The heating fractional bin hours in Table 1 of NYSERDA's response are based on archived weather data accessed from National Renewable Energy Laboratory's (''NREL'') National Solar Radiation Database (''NSRDB'') and NREL's PSM v3 TMY weather data accessed from NSRDB.

[62] Cut-out temperature refers to the outdoor temperature at which the unit compressor stops (cuts out) operation.

[63] Cut-in temperature refers to the outdoor temperature at which the unit compressor restarts (cuts in) operation.

[64] Figure 7 in the operating bulletin of the Copeland ZP*3KE and ZP*5KE R–410A scroll compressors shows their evaporating envelope, clearly indicating that they should not be used below saturated suction temperatures of −10 °F, implying that this should be set as the cut-out temperature. The bulletin is available at *climate.emerson.com/documents/ae-1331-zp16-to-zp44k3e-zp14-to-zp61k5e-r-410a-1-5-to-5-ton-copeland-scroll-compressors-en-us-1571048.pdf.*

temperature deviates from that of the ambient air (*e.g.,* downstream of the outdoor coil, which absorbs heat from the ambient air during heat pump operation). (*Id.*) As such, in the January 2023 RFI, DOE requested information on the range of cut-out temperatures for compressor operation of CAC/HPs. (*Id.)*

In response, Rheem commented that a sufficient hysteresis, or difference between cut-in and cut-out temperatures, is necessary for reliable compressor operation and in some cases is prescribed by the compressor drive manufacturer. (Rheem, No. 12 at p. 8) The CA IOUs concurred with DOE's observation that the controls and sensors can significantly impact actual cut-in and cut-out temperatures and commented in support of DOE's investigation of cut-out and cut-in temperature certification, stating that the CA IOUs had observed similar discrepancies between cut-out temperatures listed in manufacturer installation/operations materials relative to those seen under native controls in laboratory testing of packaged terminal heat pumps. (CA IOUs, No. 10 at p. 4) The Joint Advocates encouraged DOE to consider adopting a cut-in and cut-out temperature validation test (instead of relying on manufacturer-provided values), if DOE determines that the discrepancies regarding cut-out and cut-in temperatures described earlier contributes to unrepresentative ratings of seasonal heating performance. (Joint Advocates, No. 8 at p. 3)

NYSERDA also supported an approach to certify cut-out and cut-in temperatures and proposed that DOE consider recommendation 10 of the 2022 ASRAC CUAC and CUHP WG TP term sheet. (NYSERDA, No. 9 at pp. 12–13) Recommendation 10 suggests requiring manufacturers to certify cut-out and cut-in temperatures to DOE or the absence thereof, and prescribes that DOE adopt a product-specific enforcement provision that includes a verification test based on the following method:

- Outdoor air temperature (''OAT'') is measured using an outdoor coil air sampler.
- Start at an OAT above but close to cut-out temperature.
- Ramp down OAT temperature at 1 °F per 5 minutes.
- Wait for 5 minutes once unit shuts off. Cut-out temperature is the measured temperature with the unit turned off.
- Reverse temperature ramp and increase the temperature by 1 °F per 5 minutes.
- Wait for 5 minutes once the unit turns on. Cut-in temperature is the measured temperature with the unit turned on.

NYSERDA further commented that recommendation 10 could be adapted for HPs in a manner that allows adjustment to the low temperature cut-out factor specified in equation 4.2.1–3 of appendix M1, if DOE deems during its enforcement test that the measured cut-out and cut-in temperatures significantly deviate from manufacturer-certified values, thereby impacting the calculated HSPF2 value during the enforcement testing process. (NYSERDA, No. 9 at pp. 12–13)

As previously mentioned, AHRI and other stakeholders, including DOE, discussed several issues raised in the January 2023 RFI, including the topic of cut-out and cut-in temperature certification, when considering updated versions of industry standards. The information provided in the aforementioned comments was discussed in detail in the development of the AHRI 210/240–202X and AHRI 1600–202X Drafts, which, in the appendix K of their respective drafts, include a test applicable to all HPs to determine cut-out and cut-in temperatures (*i.e.,* T_{off} and T_{on} respectively). Appendix K follows recommendation 10 of the 2022 ASRAC CUAC and CUHP WG TP term sheet and includes an accommodation for those test facilities incapable of reaching OATs below −22 °F. For units with cut-out temperatures below −22 °F tested in facilities that are incapable of reaching OATs below −22 °F, appendix K instructs to (alternatively) end the test 5 minutes after the average outdoor coil air inlet temperature reaches and maintains the coldest achievable temperature below −22 °F, and to record T_{off} as this coldest achievable temperature below −22 °F. DOE surmises that this approach provided in appendix K of the relevant AHRI drafts represents industry consensus regarding a test to verify cut-out and cut-in temperatures for HPs. DOE has tentatively determined that this approach is appropriate while accounting for the capability limitations of certain test facilities. Therefore, DOE is proposing to require appendix K of the AHRI 210/240–202X Draft to support enforcement associated with testing conducted in accordance with appendix M1, and to require appendix K of the AHRI 1600–202X Draft to support enforcement associated with testing conducted in accordance with appendix M2. As further discussed in section III.J.1 of this document, DOE may verify certified cut-out and cut-in temperatures using the test methods in appendix K of the relevant AHRI drafts for the purposes of assessment and enforcement testing.

4. Low-Static Single-Split Blower-Coil System Definition and Testing Provisions

Section 3.1.4.1.1 of appendix M1 defines the minimum ESP for ducted blower-coil systems in Table 4. For conventional blower-coil systems (*i.e.,* all CAC/HPs that are not classified as ceiling-mount, wall-mount, mobile home, low-static, mid-static, small-duct high-velocity (''SDHV''), or space-constrained), the minimum ESP is specified as 0.5 in. wc. The definition for low-static blower-coil systems includes only multi-split and multi-head mini-split systems—it does not include single-split systems.

In the January 2023 RFI, DOE explained that, during the previous rulemaking cycle that culminated in the October 2022 Final Rule, stakeholders requested that the low-static blower-coil system definition be expanded to include products, such as single-split systems, that cannot accommodate the 0.5 in. wc. necessary for testing. 88 FR 4091, 4105–4106. However, in the October 2022 Final Rule, DOE did not revise the definition for low-static blower-coil systems, nor did it include any new test provisions to accommodate these system types. 87 FR 64550, 64575–64576. DOE believed that revising the definition of low-static blower-coil systems would conflict with the intent of comments made by stakeholders when establishing appendix M1, and could potentially create an unfair competitive advantage for these system types by allowing more lenient testing conditions (and thus comparatively higher ratings) as compared to conventional centrally ducted systems tested at minimum ESPs exceeding 0.5 in. wc. (*Id.*)

In the January 2023 RFI, DOE considered it appropriate to revisit the issue of extending the definition of low-static blower-coil systems to single-split systems, rather than grant test procedure waivers to allow such models to test using lower ESPs.[65] 88 FR 4091, 4106. As such, DOE requested comment from stakeholders on whether the low-static blower-coil system definition should be extended to single-split systems, and if extended, how these low-static blower-

[65] In the time since the January 2023 RFI, DOE has granted an interim waiver pending final determinations that allow testing for certain basic models of single-split low-static ducted blower-coil systems (which are incapable of meeting the conventional minimum ESP requirement of 0.5 in. wc. found in Table 4 of appendix M1). This interim waiver was granted to Samsung on June 5, 2023 (*see* 88 FR 36558).

coil systems should be differentiated from conventional systems. (*Id.*)

In response, Daikin commented in support of developing a definition with stakeholders. (Daikin, No. 16 at p. 11) Similar to the existing ''wall-mount'' and ''ceiling-mount'' blower-coil systems defined in appendix M1, Daikin commented that low-static blower-coil systems have physical and operational characteristics that could be defined such that it would not be possible for a common residential ducted blower-coil to 'cheat' the system and test at a lower ESP. (*Id.*) Daikin suggested this could be accomplished by defining physical dimensions (in a similar fashion to ''ceiling-mount'') as well as applying an appropriate maximum airflow rate per capacity (cfm per ton) at a relatively low ESP. (*Id.*)

AHRI also commented in support of the addition of a definition for single-split low-static blower-coil systems, as low static single-zone [66] units cannot accommodate the minimum 0.5 in. wc. ESP necessary to be tested using appendix M1. (AHRI No. 14 at pp. 14–15) AHRI proposed the following amended definition of a low-static blower-coil system (addition is in *italic*):

Low static blower-coil system means (a) a ducted multi split or multi head mini split system for which all indoor units produce [67] greater than 0.01 in. wc. and a maximum of 0.35 in. wc. external static pressure when operated at the cooling full load air volume rate not exceeding 400 cfm per rated ton of cooling, *or (b) a ducted single zone mini split for which the indoor unit produces a maximum of 0.25 in. wc. external static pressure not exceeding 350 cfm/ton when operated at the highest possible air flow rate and has a rated heating or cooling capacity less than 24,500 Btu/h.*

Samsung agreed with AHRI's proposed definition and requested its adoption. (Samsung, No. 11 at p. 2)

As previously mentioned, AHRI and other stakeholders, including DOE, considered several issues raised in the January 2023 RFI, including the topic of extending the definition of low-static blower-coil systems, when considering updated versions of industry test standards. The information provided in the aforementioned comments was discussed in detail in the development of the AHRI 210/240–202X Draft and AHRI 1600–202X Draft, which, rather than amend the current low-static blower-coil system definition, include a new definition specific for low-static single-split blower-coil systems as shown below.

Low-static single-split blower-coil system means a ducted single-split system air conditioner or heat pump for which all of the following apply:

(1) The Outdoor Unit has a certified cooling capacity less than or equal to 24,000 Btu/h;

(2) If the Outdoor Unit is a heat pump or a variable capacity air conditioner, it is separately certified with a blower-coil indoor unit tested with a minimum 0.5 in. wc. ESP, otherwise it is separately certified with a coil-only indoor unit; and

(3) The Indoor Unit is marketed for and produces a maximum ESP less than 0.5 in. wc. when operated at the certified cooling full-load air volume rate not exceeding 400 scfm per rated ton of cooling.

Both AHRI 210/240–202X Draft and AHRI 1600–202X Draft also include provisions instructing low-static single-split blower-coil systems to be tested at their certified airflow (not to exceed 400 scfm per rated ton of cooling capacity) at their maximum airflow setting. If the ESP achieved at the rated airflow is less than 0.1 in. wc., the provisions instruct adjustment of the airflow measurement apparatus fan to reduce airflow and increase ESP until a minimum of 0.1 in. wc. is achieved.

DOE surmises that the new definition of low-static single-split blower-coil system and associated testing provisions provided in the relevant AHRI drafts represent industry consensus regarding the issue of expanding the low-static blower-coil system definition to include products, such as single-split systems, that cannot accommodate the 0.5 in. wc. necessary for testing in appendix M1. DOE considers the new definition of low-static single-split blower-coil systems and the corresponding test requirements to be appropriate as they allow for testing of system combinations including indoor units that cannot meet the minimum ESP of 0.5 in. w.c. This approach would also require the outdoor unit to be rated when operating with a 0.5 in w.c. (or blower-coil) indoor unit, thus ensuring that the outdoor units of low-static combinations do not gain an unfair advantage due to being allowed to test with an indoor unit at a lower ESP. Therefore, DOE is proposing to incorporate by reference the new definition of low-static single-split blower-coil system and the aforementioned testing provisions outlined in the AHRI 210/240–202X and AHRI 1600–202X Drafts, at appendix M1 and appendix M2, respectively.

Should the new definition of low-static single-split blower-coil system and the associated testing provisions be adopted, DOE would terminate an interim waiver pending final determination, which allows testing for certain basic models of low-static single-split ducted blower-coil systems that are incapable of meeting the conventional minimum ESP requirement of 0.5 in. wc. found in Table 4 of appendix M1. The interim waiver was granted to Samsung on June 5, 2023 (*see* 88 FR 36558). The interim waiver granted an alternate test procedure, which instructs the manufacturer to test their specific basic models at 0.1 in. wc. ESP but to adjust the fan power [68] to reflect operation at 0.5 in. wc. ESP, consistent with the requirements of appendix M1. The alternate test procedure also instructed to adjust heating and cooling capacities [69] to account for increased fan heat. The interim waiver was granted with the understanding that it was impossible to test the manufacturers' specific basic models according to the prescribed test procedures in appendix M1, DOE surmises that this alternate test procedure would no longer be necessary should appendix M1 be amended to enable testing of the manufacturers' specific basic models. Therefore, DOE is proposing to terminate the aforementioned waiver for Samsung, should the new definition of low-static single-split blower-coil system and associated testing provisions provided in the AHRI 210/240–202X and AHRI 1600–202X Drafts be adopted.

5. Mandatory Constant Circulation Systems

In the January 2023 RFI, DOE noted that there is a potential for increased use of indoor fan constant circulation in systems that employ new refrigerants to mitigate flammability risks. 88 FR 4091, 4102. Currently, nearly all CAC/HP products are designed with R–410A as the refrigerant. The EPA Significant New Alternatives Policy (''SNAP'') Program evaluates and regulates substitutes for ozone-depleting chemicals (such as CAC/HP refrigerants)

[66] The comments used the term ''single-zone'', which is addressed by the term ''single-split'' in appendix M1.

[67] The proposed alternate definition for ''Low-Static Blower-Coil System'' in AHRI's response uses the language ''the indoor unit produce.'' (AHRI No. 14 at p. 14) DOE surmises that this is a typographical error and that AHRI meant to write ''all indoor units produce'' as is in appendix M1.

[68] In all sections of appendix M1 where total cooling capacity, total heating capacity, sensible cooling capacity, and electrical power consumption are calculated, the alternate test procedure requires the measured indoor fan power to be increased by 87 watts per 1000 scfm. (*see* 88 FR 36558).

[69] The alternate test procedure requires that, for all tests, cooling capacity be decreased by the Btu/h equivalent of the fan power adjustment (*i.e.,* 297 Btu/h per 1000 scfm); likewise, for all tests, the heating capacity be increased by the same Btu/h equivalent. (*see* 88 FR 36558).

that are being phased out under the stratospheric ozone protection provisions of the Clean Air Act. (42 U.S.C. 7401 *et seq.*) [70] Of interest to CAC/HPs, the EPA SNAP Program's list of viable substitutes [71] includes a group of refrigerants classified as A2L refrigerants. A2L refrigerants receive high attention for their low GWP in addition to their minimal to zero ozone depletion potential. However, A2L refrigerants also face stricter safety requirements than most due to the flammability concerns associated with their ''2L'' ASHRAE safety classification.[72]

Considering A2L flammability concerns and the large push toward their increased use in design, UL published updated safety standards [73] for electrical heat pumps, air-conditioners, and dehumidifiers that include the CAC/HP products at issue in this document. One safety risk these standards address is refrigerant leakage, which can be especially hazardous with A2Ls involved. In satisfaction of new UL safety requirements, manufacturers may need to adjust CAC/HP product design to include refrigerant leak detection systems that use sensors and control logic to detect a loss of pressure, activate the evaporator fan, and use circulated air to quickly disperse and dilute refrigerant in the event of a leakage. In the January 2023 RFI, DOE acknowledged that a subsequent need may exist for the constant circulation of refrigerant or circulation based on leak detection to accommodate these refrigerant leak detection and mitigation strategies in CAC/HP product design. 88 FR 4091, 4102. As such, DOE requested comment on whether UL safety requirements for A2L refrigerants will require some level of circulation on a continuous basis from a unit's indoor fan, or whether circulation to disperse refrigerant will only be required when sensors detect a leak. *Id.* DOE also expressed interest to know of any other techniques that manufacturers will use for dispersing the A2L refrigerant in the event of a refrigerant leak. *Id.*

In response, AHRI, Rheem, and Samsung all commented that constant circulation is a permitted option for A2L mitigation, but is not required. (AHRI, No. 14 at p. 12; Rheem, No. 12 at p. 6; Samsung, No. 11 at p. 2) Daikin specifically noted that UL/CSA 60335–2–40 will only require circulation in the event of detection of a refrigerant leak, which is abnormal operation, and thus not a ''typical use cycle.'' (Daikin, No. 16 at p. 8) For alternative methods of A2L mitigation, Rheem pointed to ASHRAE Standard 15–2016, Safety Standard for Refrigeration Systems (''ASHRAE 15–2016''),[74] which prescribes several methods to disperse/diffuse leaked refrigerant and allows selection of one or more methods to comply with safety standards. (Rheem, No. 12 at p. 6) Related to this topic, the CA IOUs commented that leak detection systems (which only activate the fan when required to disperse fugitive refrigerant) likely reduce a unit's energy consumption. (CA IOUs, No. 10 at p. 4)

While constant circulation may not be a required option, DOE notes that CAC/HPs may increasingly incorporate constant circulation systems in future design. As previously mentioned, AHRI and other stakeholders, including DOE, discussed several issues raised in the January 2023 RFI, including the topic of mandatory constant circulation systems, when considering updated versions of industry standards. The information provided in the aforementioned comments was discussed in detail in the development of AHRI 210/240–202X Draft and AHRI 1600–202X Draft, for which stakeholders agreed to include a new definition for ''mandatory constant circulation system,'' shown below.

Mandatory constant circulation system means an air conditioner or heat pump that operates the indoor fan continuously when power is applied to the unit regardless of control settings.

The updated industry standard drafts also include testing provisions for such systems, outlined in sections 5.1.1, 6.1.3.1.1, and 6.1.3.2.1 as well as Table 7 of both AHRI 210/240–202X Draft and AHRI 1600–202X Draft.[75] These provisions require CAC/HPs meeting the mandatory constant circulation system definition not to use the default cooling and heating degradation coefficients, but rather to evaluate these degradation coefficients using the respective cyclic tests specified by Table 7, conducted in accordance with section E12 of appendix E of AHRI 210/240–202X Draft and AHRI 1600–202X Draft. DOE surmises that the new definition of mandatory constant circulation system and the aforementioned testing provisions provided in the relevant AHRI drafts represent industry consensus regarding representative testing of those CAC/HPs that may use constant circulation to meet the safety requirements for A2L refrigerants. DOE has tentatively determined that the definition and approach included in the draft industry standards provides a more representative measure of CAC/HP efficiency for units with mandatory constant circulation systems. Therefore, DOE is proposing to incorporate by reference the new definition of mandatory constant circulation system and the aforementioned testing provisions outlined in AHRI 210/240–202X Draft and AHRI 1600–202X Draft, at appendix M1 and appendix M2, respectively.

6. Dual-Fuel Systems

Heat pumps generally perform less efficiently at low ambient outdoor temperatures than they do at moderate ambient outdoor temperatures. In the January 2023 RFI, DOE expressed awareness of HPs that combine the operation of a conventional electric HP with a back-up heating source, such as a fuel-fired furnace or boiler. 88 FR 4091, 4106. These are referred to as ''dual-fuel'' systems or hybrid heat pumps (''HHPs'') and provide an alternative to heat pumps specifically designed to perform in cold climates (*i.e.,* cold climate heat pumps). Dual-fuel systems rely on heat pump operation at milder ambient temperatures, but switch to the back-up heating source at low ambient temperatures.

Currently, the HSPF2 calculation at appendix M1 does not differ for a dual-fuel system and a HP that relies solely on vapor-compression or electric resistance auxiliary heating. However, in the January 2023 RFI, DOE explained that this may not be representative of HHP field operation since the back-up heating source takes over for much of the coldest conditions when HP efficiency would be lower. 88 FR 4091, 4106. DOE also noted that, while the focus of test procedures for cold climate heat pumps has been on evaluation of performance at colder temperatures

[70] Additional information regarding EPA's SNAP Program is available online at: *www.epa.gov/ozone/snap/.*

[71] List of EPA SNAP program-approved refrigerant substitutes is available at *www.epa.gov/snap/substitutes-residential-and-light-commercial-air-conditioning-and-heat-pumps.*

[72] ASHRAE assigns safety classification to refrigerants based on toxicity and flammability data. The capital letter designates a toxicity class based on allowable exposure and the numeral denotes flammability. For toxicity, Class A denotes refrigerants of lower toxicity, and Class B denotes refrigerants of higher toxicity. For flammability, class 1 denotes refrigerants that do not propagate a flame when tested as per the standard; classes 2 and 2L denote refrigerants of lower flammability; and class 3 denotes highly flammable refrigerants (such as hydrocarbons).

[73] On November 1, 2019, UL published an updated 3rd edition of UL 60335–2–40 that includes safety requirements regarding the use A2L refrigerants in CAC/HP product design.

[74] ASHRAE 15–2016 is available for purchase at *www.techstreet.com/ashrae/standards/ashrae-15-2016-packaged-w-34-2016?product_id=1938420.*

[75] DOE notes that additional testing provisions for mandatory constant circulation systems are included in the AHRI 1600–202X Draft, which are separately discussed and proposed to be adopted in section III.F.1.e) of this NOPR.

(*e.g.,* the optional 5 °F test condition) to incentivize improved cold-temperature performance, incentivizing efficiency improvement for HHPs might more appropriately focus on warmer conditions, potentially temperatures warmer than 17 °F. (*Id.*)

In the January 2023 RFI, DOE requested information on the prevalence of HHP systems (including shipment numbers and shipment breakdown among single-stage, two-stage and variable-capacity) and the climates they are most used in. 88 FR 4091, 4106. Additionally, DOE requested information on how the controls for HHPs are generally set up to provide dual functionality—specifically, whether the furnace is just set at a higher stage, or whether there is a crossover temperature below which the HP isn't used; if so, the range of crossover temperatures and whether these systems have electric resistance auxiliary heaters. (*Id.*) DOE also requested feedback on whether it is more appropriate to adjust the HSPF2 to address actual operation of the heat pump or just to emphasize performance only in heat pump mode (*i.e.,* when the back-up source is not operating). (*Id.*)

In response, AHRI and Daikin both suggested that a proper definition and scope for HHP products should be developed if modifications to appendix M1 are made to address HHPs. (AHRI, No. 14 at pp. 3–4; Daikin, No. 16 at p. 11) Daikin commented that, while the most common HHPs, dual-fuel systems, have a temperature-based changeover where the heat pump stops operating and the gas furnace takes over, other HHPs may not always follow that model and may operate the gas furnace simultaneously with the heat pump under certain conditions. (Daikin, No. 16 at p. 11) Similarly, AHRI commented that, in most cases, accessory control tries to satisfy the set point temperature with the heat pump by itself, and, when unable to satisfy the set point, it will turn off the heat pump and turn on the furnace. (AHRI, No. 14 at p. 15) AHRI also noted that the heat pump lock-out temperature is typically set by the homeowner in the accessory control. (*Id.*)

AHRI and Rheem both commented in support of a credit for dual-fuel systems in the HSPF2 calculation and noted that dual-fuel systems do not typically have electric resistance heaters. (AHRI, No. 14 at p. 15; Rheem, No. 12 at pp. 8–9) AHRI commented that dual-fuel heat pumps and HHPs offer a lower carbon heating solution that may pose other benefits as well. (AHRI, No. 14 at pp. 3–4) AHRI commented that electrification with fuel backup provides resiliency to the energy grid, particularly in locations where the grid is designed to accommodate summer peaking loads. (*Id.*) AHRI also commented that moving the thermal load from gas to electric results in a significant increase in peak electric demand in winter. (*Id.*)

NYSERDA commented against including a credit for HHPs in the HSPF2 calculation, noting that an HSPF2 credit adjustment would serve to encourage the use of switch-over controls that operate at a higher outdoor ambient temperature, which is at odds with maximizing heat pump performance and limits the decarbonization potential of heat pumps. (NYSERDA, No. 9 at p. 13) NYSERDA suggested a certification approach, which would incentivize an integrated control that optimally locks out auxiliary heating options (electric or gas) until it is no longer feasible for the HP to heat the space via only the vapor-compression cycle. (*Id.*) NYSERDA also recommended that DOE work to encourage lower temperature settings for the switchover device of a HHP whenever possible in the structure of the test procedure. (*Id.*) NYSERDA suggested that certification of cut-in and cut-out temperatures may help address some aspects of the issues presented in the January 2023 RFI regarding HHPs. (*Id.*) However, NYSERDA also stated that it has found manufacturer's lowest catalogued temperature (''LCT'') in the engineering tables may be more important in practice than the cut-out and cut-in temperatures, which are often quite low. (*Id.*) While it acknowledged that cut-out and cut-in temperatures are useful for planning equipment applications and should be accounted for in bin model calculations of HSPF2, NYSERDA recommended using the LCT, the lowest temperature at which a manufacturer will stand behind its capacity and that DOE require the HSPF2 bin model always attribute a COP of 1 for any bin temperature below the LCT of a tested product. (*Id.*)

NEEA recommended that DOE continue to explore HHP ratings that focus on maximizing time spent in electric heat pump mode before switching over to supplemental heating and suggested that on-board controls, which learn and adjust the crossover temperature based on performance, could earn a higher efficiency rating. (NEEA, No. 13 at p. 8)

As previously mentioned, AHRI and other stakeholders, including DOE, discussed several issues raised in the January 2023 RFI, including the topic of dual-fuel systems, when considering updated versions of industry standards. The information provided in the aforementioned comments was discussed in detail in the development of AHRI 210/240–202X Draft and AHRI 1600–202X Draft, which include a new definition for ''dual-fuel heat pump,'' shown below.

Dual-fuel heat pump means A central air conditioning heat pump consisting of (a) a rated combination of outdoor heat pump unit, of any type covered within this standard, (b) an indoor coil and (c) a furnace certified to DOE as an air mover and backup heat source.

Additionally, AHRI 210/240–202X Draft and AHRI 1600–202X Draft introduce a new seasonal efficiency metric, Dual Fuel Utilization Efficiency (''DFUE''), meant to capture the heating efficiency of such dual-fuel heat pump systems. Calculation of DFUE is optional, requires no additional testing, and is outlined in appendix L of both AHRI 210/240–202X Draft and AHRI 1600–202X Draft.

DOE has tentatively determined that the definition and optional test approach included in the draft industry standards may provide a representative test approach for dual-fuel heat pump systems, but DOE is continuing to evaluate whether to include such provisions in its CAC/HP test procedures. Therefore, DOE is not proposing to incorporate by reference the new definition of dual-fuel heat pump and the optional seasonal efficiency metric, DFUE, outlined in the AHRI 210/240–202X and AHRI 1600–202X Drafts at this time.

DOE notes that since dual-fuel heat pump systems are comprised of two covered products currently subject to energy conservations standards (*i.e.,* a heat pump and a furnace), DOE would continue to require reporting of the relevant CAC/HP and consumer furnace heating metrics—HSPF2 and SHORE for CAC/HP, and AFUE for consumer furnaces—but recognizes that representations of dual-fuel heat pump performance may be useful to consumers. DOE is not proposing provisions for dual-fuel heat pumps, but would allow manufacturers to make optional representations of dual-fuel heat pump performance consistent with available industry test standards.

7. Provisions for Outdoor Units With No Match

For split-system CAC/HPs, section 2.2.e of appendix M1 requires that an outdoor unit with no match (''OUWNM'') (*i.e.,* outdoor units that are not distributed in commerce with any indoor units) be tested using a coil-only indoor unit with a single cooling air volume rate whose coil has round tubes of outer diameter no less than 0.375

inches, and normalized gross indoor fin surface (''NGIFS'', gross indoor fin surface divided by the measured cooling capacity) no greater than 1.0 square inch per British thermal unit per hour (sq. in./Btu/hr). (10 CFR 429.16 (b)(2)(i) and appendix M1, section 2.2.e) These provisions were introduced in a final rule regarding CAC/HP test procedures published on June 8, 2016 (''June 2016 Final Rule''), to address outdoor-unit-only replacements of old R–22 outdoor units. 81 FR 36992, 37008–37012. Effective January 1, 2010, EPA banned sales and distribution of CAC/HPs designed to use R–22, a hydrochlorofluorocarbon (''HCFC'') refrigerant, that causes ozone depletion. 74 FR 66450 (Dec. 15, 2009). However, EPA continued to allow sale and distribution of ''components'' of CAC/HP systems for repair purposes, such as outdoor units. *Id.* at 74 FR 66452. In the June 2016 Final Rule, DOE introduced the testing provisions for OUWNM to ensure that performance ratings for such installations would be representative of the replacement of outdoor units originally designed for R–22 and using the original indoor units. *See* 81 FR 36992, 37008–37011.

While these OUWNM provisions were precipitated by EPA's ruling on R–22 units, DOE's intention was to apply them more broadly to any case where an outdoor unit is sold without an indoor unit. In the June 2016 Final Rule, DOE noted that its test provisions were introduced to ensure that an unmatched outdoor unit would be compliant when tested with an indoor unit that is representative of indoor units in the field with which the outdoor unit could be paired. 81 FR 36992, 37009. DOE designed these requirements to meet the statutory requirement that the test procedure measure a representative average use cycle. *Id.* DOE noted that the indoor unit specifications represent lower-efficiency indoor units that would be paired with a given outdoor unit with no match. *Id.* DOE believed this approach was consistent with the requirement that the represented value for a basic model reflect the performance of the poorest-performing model that is part of the basic model. *Id.*

In a final rule published on October 24, 2023 (''October 2023 EPA Final Rule''), EPA, pursuant to provisions of the American Innovation and Manufacturing Act, enacted on December 17, 2020 (42 U.S.C. 7675), restricted the installation of residential and light commercial systems that are designed for hydrofluorocarbon (''HFC'') refrigerants having a GWP greater than 700, starting January 1, 2025. 88 FR 73098. On December 26, 2023, EPA published an amendment to the October 2023 EPA Final Rule that extended the installation deadline to January 1, 2026 as long as the components being installed were manufactured or imported prior to January 1, 2025. 88 FR 88825. Split-system CAC/HPs are included in the scope of residential and light commercial systems. As such, split-system CAC/HPs designed for use with R–410A and sold as a combination of an outdoor and indoor unit, would be banned for installation per the October 2023 EPA Final Rule. However, EPA allows consumers and businesses to replace, retrofit, and service components of existing systems that are over the GWP limits defined in the October 2023 EPA Final Rule to ensure that new equipment with lower-GWP refrigerants is phased in only when all components of the older equipment reach the end of their functional life. 88 FR 73089, 73202. Hence, this provides an exemption for individual components of R–410A based split-system CAC/HP to be sold as replacements, similar to the component exemption adopted when R–22 was phased out. 74 FR 66450, 66459–66460.

As noted, DOE's OUWNM provisions apply for any outdoor units that are distributed in commerce without an indoor matching pair, regardless of the refrigerant the outdoor unit employs. Therefore, DOE clarifies that because of the October 2023 EPA Final Rule, any outdoor unit designed for R–410A or any banned refrigerant as per EPA regulations, when distributed in commerce without an indoor unit on or after January 1, 2026, would be deemed an outdoor unit with no match, precisely because the October 2023 EPA Final Rule allows installation of such outdoor units only as no-match replacements. As EPA provided for after the R–22 ban, such outdoor units may be installed as a replacement component for an existing system but may not be sold with indoor units for installation as a complete split CAC/HP system.

Although the current provisions for an outdoor unit with no match in appendix M1, 10 CFR 429.16, and 10 CFR 429.70 were finalized in the June 2016 Final Rule, DOE notes that appendix M1 currently does not explicitly define outdoor units with no match. While AHRI 210/240–202X Draft and AHRI 1600–202X Draft define outdoor units with no match, the definition applies explicitly only to R–22 replacement outdoor units and outdoor units using refrigerants with properties similar to R–22. This was because the initial establishment of the outdoor unit with no match provisions occurred in the wake of the R–22 ban. In light of the October 2023 EPA Final Rule, DOE is clarifying that similar treatment is applicable to replacement outdoor units designed for use with R–410A, and any other refrigerants banned by EPA for full system installations. Because the definition of outdoor unit with no match in AHRI 210/240–202X Draft and AHRI 1600–202X Draft is specifically focused on R–22 outdoor units, DOE is not incorporating the definition by reference, and is instead proposing a clarifying definition that is consistent with DOE's intention in the June 2016 Final Rule. The proposed definition for appendix M1 is as follows:

Outdoor Unit with No Match (OUWNM). An Outdoor Unit that is not distributed in commerce with any indoor units, and that meets any of the following criteria:

(a) is designed for use with a refrigerant that makes the unit banned for installation when paired with an Indoor Unit as a system, according to EPA regulations in 40 CFR chapter I, subchapter C,

(b) is designed for use with a refrigerant that has a 95 °F midpoint saturation absolute pressure that is ±18 percent of the 95 °F saturation absolute pressure for R–22, or

(c) is shipped without a specified refrigerant from the point of manufacture or is shipped such that more than two pounds of refrigerant are required to meet the charge per section 5.1.8 of AHRI 210/240–202X Draft. This shall not apply if either (a) the factory charge is equal to or greater than 70% of the outdoor unit internal volume times the liquid density of refrigerant at 95 °F or (b) an A2L refrigerant is approved for use and listed in the certification report.

The proposed definition of OUWNM for appendix M2 is the same as that for appendix M1, except that the reference in part (c) of the definition is to section 5.1.8 of AHRI 1600–202X Draft.

DOE is proposing separate definitions in appendix M1 and appendix M2 because part of the definitions refer to sections of the relevant AHRI standards that are incorporated by reference (*i.e.,* AHRI 210/240–202X Draft for appendix M1, and AHRI 1600–202X Draft for appendix M2). Additionally, since the terms ''outdoor unit'' and ''indoor unit'' appear in the definition of outdoor unit with no match, DOE proposes to incorporate by reference the definitions for them from AHRI 210/240–202X Draft and AHRI 1600–202X Draft.

DOE tentatively concludes that the above definitions would further help clarify that the existing test procedure

and rating requirements for outdoor units with no match are applicable to R–410A based systems, and any other refrigerants banned by EPA regulations from January 1, 2026, as they have been previously, for R–22 and any other ozone depleting refrigerants. The proposed definitions would apply to all types of outdoor units (*i.e.,* heat pump, air conditioner, single-speed, two-speed, variable-speed, etc.). Outdoor units with no match would continue to be tested with an indoor coil having nominal tube diameter of 0.375 in and an NGIFS of 1.0 or less (as determined in section 5.1.6.3 of AHRI 210/240–202X Draft and AHRI 1600–202X Draft). The determination of represented values, AEDM requirements, combinations selected for testing, and certification report requirements applicable to outdoor units with no match would remain the same as those specified in Table 1 to paragraph (a)(1), paragraph (c)(2), Table 2 to paragraph (b)(2)(i), and paragraph (e)(3), respectively in 10 CFR 429.16. Existing outdoor models currently distributed in commerce as part of a split system basic model that transition to a replacement outdoor unit only would need to be tested, rated, and recertified under the provisions in 10 CFR 429.16 for an outdoor unit with no match. The basic model number would need to change to reflect that the outdoor unit is no longer part of a combination as previously certified, but rather as an outdoor unit with no match, but the outdoor unit model could still be assigned the same individual model number.

8. Inlet and Outlet Duct Configurations

In the June 2016 Final Rule, DOE made the following amendments regarding inlet and outlet duct configurations: clarified indoor unit air inlet geometry; ensured that the inlet plenum is not installed upstream of the airflow prevention device; and specified that the minimum lengths of inlet plenum, locations of static-pressure taps, and minimum cross-sectional dimensions are consistent with ANSI/ASHRAE 37–2009. 81 FR 36992, 37037. DOE also clarified that when an inlet plenum is not used, then the length of straight duct upstream of the unit's inlet within the airflow prevention device must still adhere to the inlet plenum length requirements as illustrated in ANSI/ASHRAE 37–2009, Figures 7b, 7c, and 8. (*Id.*)

In response, as discussed in the January 2017 Final Rule, stakeholders commented that DOE's clarification of inlet plenum may result in the overall height of unit setup exceeding the current height limit of many existing psychrometric rooms. 82 FR 1426, 1463. These stakeholders proposed that DOE consider allowing the approach included in ASHRAE's Research Project (''RP'') 1581, requesting DOE to approve the use of the 6″ skirt coupled with the 90° square vane elbow, along with the appropriate outlet duct. *Id.*

In the January 2023 RFI, DOE sought test data that shows testing done using reduced overall height of the unit setup (similar to that proposed in ASHRAE RP 1581) and compared against the baseline duct designs in ANSI/ASHRAE 37–2009 Figures 7b and 7c for blower-coil indoor units, and Figure 8 for coil-only indoor units. 88 FR 4091, 4105. DOE also requested information that could help inform the existing CAC/HP test procedures to allow testing in smaller environmental chambers, or to incorporate adjustments to the test setup that might reduce test burden. (*Id.*) DOE did not receive any such test data in responses to the January 2023 RFI. However, AHRI, Daikin, and Rheem all commented in support of including updates from the newest draft version of ASHRAE Standard 37 into the test procedure, which includes revisions investigated in RP 1581. (AHRI, No. 14 at p. 14; Daikin, No. 16 at p. 10; Rheem, No. 12 at p. 8) Stakeholders also commented in support of including revisions investigated in RP 1743, which explored reduced-length, alternative inlet duct configurations. (*Id.*)

In May 2023, ASHRAE released for public review its first draft of a new version of ANSI/ASHRAE Standard 37 (''May 2023 ASHRAE 37 Draft''), which includes both RP 1581 and RP 1743 updates in section 6.4 of the standard. Subsequently, AHRI and other stakeholders, including DOE, worked to include these updates in AHRI 210/240–202X Draft and AHRI 1600–202X Draft. Both appendix D of the AHRI 210/240–202X Draft and appendix D of the AHRI 1600–202X Draft contain May 2023 ASHRAE 37 Draft updates regarding inlet and outlet duct configurations, including the duct revisions investigated in RP 1581 and RP 1743 to accommodate smaller environmental chambers. DOE surmises that the inclusion of these May 2023 ASHRAE 37 Draft updates in appendix D of the relevant AHRI drafts represents industry consensus regarding inlet and outlet duct configurations. Additionally, DOE has tentatively determined that the updates included in the May 2023 ASHRAE 37 Draft are appropriate for CAC/HP testing while limiting testing burden. Consequently, DOE is proposing to incorporate by reference appendix D of AHRI 210/240–202X Draft at appendix M1 and to incorporate by reference appendix D of AHRI 1600–202X Draft at appendix M2.

DOE notes that AHRI 210/240–202X Draft and AHRI 1600–202X Draft reference the current version of ASHRAE Test Standard 37, ANSI/ASHRAE 37–2009, because the May 2023 ASHRAE 37 Draft has not yet been finalized and published. DOE notes that it may choose to update its incorporation by reference to the final published version of the May 2023 ASHRAE 37 Draft in a future rulemaking.

9. Heat Comfort Controllers

A heat comfort controller enables a heat pump to regulate the operation of the electric resistance elements such that the air temperature leaving the indoor section does not fall below a specified temperature (*see* section 1.2 of appendix M1).

Section 3.6.5 of appendix M1 includes test instructions for testing heat pumps having a heat comfort controller. Section 4.2.5 of appendix M1 includes additional steps for calculating the HSPF2 of heat pumps having a heat comfort controller, and covers the following system types:

(1) heat pumps having a single-speed compressor and either a fixed-speed indoor blower or a constant-air-volume-rate indoor blower installed;

(2) single-speed coil-only system heat pumps;

(3) heat pumps having a single-speed compressor and a variable-speed, variable-air-volume-rate indoor blower;

(4) heat pumps having a two-capacity compressor;

Unlike the other aforementioned system types having a heat comfort controller, appendix M1 does not currently specify additional steps for calculating the HSPF2 of heat pumps having a heat comfort controller and having a variable-speed compressor. However, section 4.2.5.4 of appendix M1 is reserved for potential additional steps for calculating HSPF2 for this system type. This section was initially reserved in appendix M in the CAC/HP test procedure final rule published on October 11, 2005. 70 FR 59122 (''October 2005 Final Rule'').

In the January 2023 RFI, DOE requested information on the prevalence of HP systems that include heat comfort controllers. 88 FR 4091, 4105. DOE also requested feedback on whether the heat comfort controller test approach in appendix M1 is utilized by manufacturers, and if yes, whether it needs to be updated. (*Id.*)

In response, Rheem commented that heat comfort controllers are typically

found on premium CAC/HPs, many of which are variable-speed. (Rheem, No. 12 at p. 8) However, Rheem also noted that since no additional steps for calculating the HSPF2 of heat pumps having a variable-speed compressor and a heat comfort controller are specified in the appendix M1 test procedure, there is limited utilization of the heat comfort controller test approach in appendix M1. (*Id.*) AHRI commented that it was unable to provide information regarding the current prevalence of heat comfort controllers due to time constraints but suggested that DOE require manufacturers notify consumers of the additional impacts to power consumption that come with the purchase of a heat comfort controller. (AHRI, No. 14 at p. 14)

As previously mentioned, AHRI and other stakeholders, including DOE, considered several issues raised in the January 2023 RFI, including the topic of heat comfort controller provisions, when considering updated versions of industry test standards. The information provided in the aforementioned comments was discussed in detail in the development of AHRI 210/240–202X Draft and AHRI 1600–202X Draft. Neither the AHRI 210/240–202X Draft nor the AHRI 1600–202X Draft include any changes to the heat comfort controller testing provisions for the following system types:

(1) heat pumps having a single-speed compressor and either a fixed-speed indoor blower or a constant-air-volume-rate indoor blower installed;

(2) single-speed coil-only system heat pumps;

(3) heat pumps having a single-speed compressor and a variable-speed, variable-air-volume-rate indoor blower;

(4) and heat pumps having a two-capacity compressor.

However, AHRI 210/240–202X Draft and AHRI 1600–202X Draft now specify additional steps for calculating the HSPF2 and SHORE of heat pumps having a variable-capacity compressor and a heat comfort controller. These additional steps are similar to the additional steps for calculating the HSPF2 and SHORE of other system types having a heat comfort controller. DOE has tentatively determined that the inclusion of these additional steps for calculating HSPF2 and SHORE is appropriate for heat pumps having a variable-capacity compressor and a heat comfort controller because these provisions provide a representative measures of unit operation when installed with heat comfort controllers. Therefore, DOE is proposing to incorporate by reference the additional steps for calculating the HSPF2 of heat pumps having a variable-capacity compressor and a heat comfort controller outlined in section 11.2.2.5 of AHRI 210/240–202X Draft, at appendix M1. Likewise, DOE is proposing to incorporate by reference the additional steps for calculating the SHORE of heat pumps having a variable-capacity compressor and a heat comfort controller outlined in section 11.2.2.5 of AHRI 1600–202X Draft, at appendix M2.

G. Long-Term Changes in the CAC Test Procedure

The following sections discuss issues that affect the CAC/HP test procedure in the long-term—*i.e.,* they will be effective when new CAC/HP standards are established denominated in terms of the metrics in appendix M2, SCORE, and SHORE. As previously explained, these long-term revisions would be implemented at appendix M2 via incorporation by reference of the relevant industry consensus test procedure, AHRI 1600–202X Draft. DOE has reviewed the AHRI 1600–202X Draft in relevance to its proposed to incorporate the standard by reference at appendix M2, and has tentatively concluded that it satisfies the EPCA requirement that test procedures should not be unduly burdensome to conduct and should be representative of an average use cycle. (42 U.S.C. 6293(b)(1)(A)) These long-term amendments in appendix M2 would alter the measured efficiency of CAC/HPs and would require representations in terms of new cooling and heating test metrics, SCORE and SHORE, respectively.

Additionally, DOE clarifies that all proposals related to near-term issues discussed in section III.F of this document also apply to appendix M2.

1. Power Consumption of Auxiliary Components

In the January 2023 RFI, discussed consideration of reflecting the power consumption of auxiliary components in the SEER2 and HSPF2 efficiency metrics for CAC/HPs, at the recommendation of a comment made by the CA IOUs during the limited scope rulemaking that culminated in the October 2022 Final Rule. 88 FR 4091, 4102–4103. To help DOE further assess whether its test procedure adequately addresses crankcase heater (and other auxiliary component) energy use, DOE requested information and data from stakeholders regarding the power consumption of crankcase heaters and other auxiliary components in the January 2023 RFI. 88 FR 4091, 4102–4103. The sections below address a range of topics associated with power consumption of auxiliary components.

In addition, in the January 2023 RFI, DOE also requested information and available field data on any auxiliary components other than crankcase heaters that come equipped with CAC/HPs that use energy or affect systems energy use. 88 FR 4091, 4103. In response, Rheem commented that the off-mode power measurement per appendix M1 would account for leak sensor power consumption if leak sensors are required to be installed in the system during testing. (Rheem, No. 12 at p. 7) Additionally, Rheem commented that base pan heaters can only be installed by the factory, while other accessories, such as UV lights and electrostatic filters, are typically field installed. (*Id.*)

As previously mentioned, AHRI and other stakeholders, including DOE, discussed several topics included in the January 2023 RFI, including the topic of accounting for auxiliary components' power consumption, when considering updated versions of industry standards. The information provided by stakeholders in comments, summarized in the following subsections, was discussed in detail in the development of the AHRI 1600–202X Draft, which accounts for crankcase heater, base pan heater, and constant circulation fan energy consumption (as applicable) in the calculations of the new cooling and heating performance metrics, SCORE and SHORE. As part of the proceedings to develop the AHRI 1600–202X Draft, manufacturers provided survey data regarding auxiliary components, their prevalence and their wattages, and the group conducted analysis to determine which auxiliary components not yet addressed in the current DOE test procedure should be considered.

(a) General Comments About Standby and Off Mode Power Consumption

In response to the January 2023 RFI, the CA IOUs and NYSERDA both requested that DOE revisit the issue of accounting for the standby mode energy consumption of auxiliary components in appendix M1. (CA IOUs, No. 10 at p. 2; NYSERDA No. 9 at p. 7) NYSERDA requested elaboration on the justification for DOE's conclusion in the January 2023 RFI that standby mode energy consumption is addressed in the off-mode power consumption calculations in section 4.3 of appendix M1. (NYSERDA, No. 9 at p. 7) NYSERDA commented that it seeks this clarification because DOE had previously summarized that standby mode is addressed in the part load SEER and HSPF metrics in both the August

2016 SNOPR[76] and the June 2016 Final Rule.[77] (*Id.*) Further, NYSERDA noted that, in the June 2016 Final Rule, DOE previously reviewed IEC Standard 62301 and determined that the procedures contained therein are not sufficient to properly measure off mode power for the unique characteristics of the components that contribute to off-mode power for CAC/HP products (*i.e.,* the crankcase heaters).

Daikin commented that, in line with the general principle floated in the recent commercial unitary air conditioner (''CUAC'') and commercial unitary heat pump (''CUHP'') (collectively, ''CUAC/HP'') rulemaking,[78] a seasonal metric should measure all capacity delivered divided by all power consumed; and there should be a single seasonal metric for cooling and a single seasonal metric for heating to encompass all energy consumption, eliminating secondary metrics such as energy efficiency ratio (''EER'') and off-mode power (''$P_{W,OFF}$''). (Daikin, No. 16 at p. 7)

NYSERDA commented that, while further consideration to off-mode energy consumption may not be strictly necessary for CAC/HPs (because appendix M1 already includes off-mode provisions), it urges DOE to consider a more comprehensive approach to standby mode. (NYSERDA, No. 9 at pp. 7–8) NYSERDA recommended the inclusion of crankcase heater power in seasonal efficiency ratings that include shoulder periods. (*Id.*)

DOE notes that, while IEC Standard 62301 and EPCA (*see* 42 U.S.C. (gg)(1)) define both standby mode and off mode for energy-using products such as air-conditioners and heat pumps, DOE defined only ''off mode'' in its test procedures for CAC/HPs. ''Off mode power consumption'' is defined as the power consumption when the unit is connected to its main power source but is neither providing cooling nor heating to the building it serves. Thus, off-mode power consumption can be considered to include power consumption associated with any system components (*e.g.,* crankcase heaters, fans, controls, base pan heaters, etc.) during any times that neither cooling nor heating are being provided, including shoulder season, heating season for a cooling-only air-conditioner, and times when the compressor is not operating (*e.g.,* during an off-cycle during a cooling or heating season). While some of the system modes during these times could be seen as complying with the EPCA definition for standby mode, the appendix M1 test procedure uses the single term ''off mode'' to refer to all of these modes. Discussion about these modes for central air conditioner and heat pumps has often used both the terms ''standby'' and ''off,'' even though they are both, per appendix M1, defined as ''off mode.''

Thus, in response to NYSERDA, DOE clarifies that standby power consumption (per appendix M1, ''off-mode'' power consumption) is indeed incorporated to an extent in the SEER2 and HSPF2 metrics, and that some of the off-mode power consumption is separately regulated by the off-mode power metric, $P_{W,OFF}$. As noted in a footnote of the January 2023 RFI, some energy use associated with crankcase heaters may be measured in the cyclic cooling test (for non-temperature dependent crankcase heaters) and cyclic heating test in appendix M1. 88 FR 4091, 4102. The energy use of auxiliary components such as control boards, reversing valves, and electronic expansion valves would also be captured during the off cycle during cyclic testing. Hence, some off mode energy consumption is captured in the SEER2 and HSPF2 metrics. However, DOE acknowledges that not all off mode energy consumption is captured by the SEER2 and HSPF2 metrics because the calculations for these metrics do not account for all the hours in a year. Specifically, shoulder-season energy use of auxiliary components is not captured consistent with the number of hours that such components may be energized (*e.g.,* for hours representing outdoor temperatures between 54.5 °F and 64.5 °F). In response, as detailed in section III.F.1.e of this NOPR, DOE is proposing to incorporate by reference the AHRI 1600–202X Draft at appendix M2, which addresses additional standby and off-mode power consumption in the SCORE and SHORE metrics, including base pan heaters and indoor fans that are required to operate in constant circulation mode to address A2L refrigerant requirements. The test standard also provides a more comprehensive way to include all significant standby and off-mode energy use, including that of crankcase heaters, in the efficiency metrics, in a way that is similar to the approach described in recommendation 13 of the 2022 ASRAC CUAC and CUHP WG TP term sheet.[79] Specifically, the SCORE and SHORE efficiency metrics both represent conditioning provided during the cooling or heating season, respectively, divided by relevant energy use associated with all components that contribute significantly to energy use.

(b) Adjustment of Off Mode Power Consumption for Number of Compressors, System Capacity, and Variable Speed and Weighting of Off-Mode Test Power Measurements

In response to the January 2023 RFI, the CA IOUs requested that DOE consider removing the adjustment factors for off-mode power consumption, and, instead, change the requirement for off-mode power consumption to a maximum allowed power consumption table based on system capacity, number of compressors, and stages. (CA IOUs, No. 10 at pp. 2–3)

The CA IOUs also recommended that the P_1 and P_2 components of $P_{W,OFF}$ be weighted based on the population-weighted number of hours where the outdoor temperature is less than 70 ^{0}F, instead of simply averaged. (CA IOUs, No. 10 at p. 3) Aligning with the data presented in Table 2 of their response,[80] the CA IOUs stated that this approach would change the weighting from 50-percent P_1 and 50-percent P_2 (a simple average) to 30-percent P_1 and 70-percent P_2. (*Id.*)

DOE notes that the modified approach for off-mode energy consumption in AHRI 1600–202X Draft, which DOE proposes to incorporate by reference, addresses both of these points, as discussed in section III.G.1.e of this NOPR.

(c) Crankcase Heaters

Regarding crankcase heaters, in the January 2023 RFI, DOE requested information as to what percentage of units on the market (split separately

[76] *See* 81 FR 58163, 58165. DOE noted, ''for CAC/HP, standby mode is incorporated into the SEER and HSPF metrics, while off mode power consumption is separately regulated. This SNOPR includes proposals relevant to the determination of both SEER and HSPF (including standby mode) and off mode power consumption.''

[77] *See* 81 FR 36992, 36994. DOE noted, ''for central air conditioners and heat pumps, standby mode is incorporated into the SEER metric, while off mode power consumption is separately regulated. This final rule includes modifications relevant to the determination of both SEER (including standby mode) and off mode power consumption.''

[78] *See* 88 FR 56392 for the most recent NOPR regarding CUAC/HPs published on August 17, 2023.

[79] Recommendation 13 of the 2022 ASRAC CUAC and CUHP WG TP term sheet requires manufacturers to certify crank case heat watts for each heater in the certified CUAC/CUHP, where each of the certified wattages must be within 10% of the maximum heater wattage determined according to the CUAC/CUHP TP at the tested nameplate voltage

[80] Table 2 of the CA IOUs response to the January 2023 RFI includes data taken from ASHRAE Standard 169–2021, *Climatic Data for Building Design Standard,* and the United States Census Bureau, with additional analysis performed by CA IOUs. (CA IOUs, No. 10 at p. 3)

between air conditioners and heat pumps) are shipped from the factory with crankcase heaters; what percentage have crankcase heaters installed in the field (*e.g.,* by contractors); and the percentage breakdown of controls used with units (both factory- and field-installed)—by those that are energized at full power during the compressor off cycle, those that also have an ambient thermostat to prevent use when temperature is high, and those that are self-regulating. 88 FR 4091, 4102–4103.

In response, Daikin commented that the majority (shipment volume) of air conditioners do not have crankcase heaters, while nearly all heat pumps do have crankcase heaters. (Daikin, No. 16 at p. 8) Daikin stated that the use of crankcase heaters typically correlates with higher refrigerant charge quantities, and that, as a result, higher efficiency AC units, with higher refrigerant charge quantities, are more likely to have crankcase heaters than lower efficiency ones. (*Id.*) Further, Daikin commented that long-line set applications, such as multi-story apartment buildings, would be the most common applications of field-installed crankcase heaters—again due primarily to the additional refrigerant charge required in those applications. (*Id.*) Rheem estimated that less than 10 percent of factory units have crankcase heaters and commented that it believes field installations for crankcase heaters to be infrequent, but depends on the length of refrigerant line set for a given installation. (Rheem, No. 12 at pp. 6–7)

The CA IOUs, NEEA, and NYSERDA all recommended that DOE account for crankcase heater energy use by aligning with recommendation 13 of the 2022 ASRAC CUAC and CUHP WG TP term sheet. (CA IOUs, No. 10 at p. 2; NEEA, No. 13 at p. 8; NYSERDA, No. 9 at pp. 10–12) Recommendation 13 of the 2022 ASRAC CUAC and CUHP WG TP term sheet suggests that DOE require manufacturers to certify crankcase heater wattage for each heater, and that each wattage certified be within 10 percent of the maximum wattage for that heater as determined in accordance with the test procedure at the tested nameplate voltage. Further, equipment that does not employ crankcase heating shall certify a value of zero.

In response, DOE notes that accounting for crankcase heater energy use for CUAC/CUHPs differs from such accounting for CAC/HPs in two fundamental ways that make recommendation 13 of the CUAC/CUHP WG TP term sheet inappropriate for this test procedure. First, CUACs and CUHPs generally have more than one compressor, often three or four compressors, whereas nearly every CAC/HP has just one. Second, control of crankcase heaters in CUACs and CUHPs, as discussed in the WG discussions is much more straightforward than for CAC/HPs. Specifically, the crankcase heaters for CUACs and CUHPs are nearly exclusively controlled to be on when the compressor is off and off when the compressor is on, with no consideration of shutoff for warm temperatures, and no significant use of self-regulating heater designs. Thus, it is both possible and necessary to conduct testing to understand CAC/HP crankcase energy use—possible because of the single compressor (and crankcase heater), and necessary to understand the control. The certification of crankcase heater wattages, as was adopted CUACs and CUHPs to avoid the additional test burden to testing multiple heaters, would not reduce the need for testing in the case of CAC/HPs. Although this rulemaking does not specifically address certification, DOE may consider certification requirements for crankcase heater wattages in a separate rulemaking.

Similar to ratings in SPE07, NYSERDA suggested that crankcase heaters and drain pan heaters (if present) could be included in the test procedure as separate tests and appropriately attributed to efficiency metrics depending on their specific control strategy. (NYSERDA, No. 9 at p. 8) NYSERDA suggested this approach, commenting it could be employed in the DOE procedure without causing a wholesale change in operating test procedures. (*Id.*)

DOE responds that the test procedure as included in AHRI 1600–202X Draft, which DOE proposes to incorporate by reference in the CAC/HP test procedure, addresses crankcase heaters (and base pan heaters if present) in a way that is consistent with the approach recommended by NYSERDA. The information provided in the aforementioned comments was discussed in detail in the development of the AHRI 1600–202X Draft, which accounts for crankcase heater power consumption in the new cooling and heating metrics, SCORE and SHORE. The AHRI 1600–202X Draft provisions that account for crankcase heater power consumption are detailed in section III.G.1.e of this NOPR.

In the August 2016 SNOPR, DOE revised the off-mode test procedure by imposing time delays to allow self-regulating crankcase heaters to approach equilibrium. 81 FR 58163, 58173–58174. Specifically, DOE proposed a 4-hour time delay for units without compressor sound blankets and an 8-hour time delay for units with compressor sound blankets. (*Id.*) DOE proposed these time delays based on testing of a 5-ton residential condensing unit. (*Id.*) In response to stakeholder comments regarding the aforementioned time delays, DOE decided in the January 2017 Final Rule to adopt the proposed time delays for measurements of off-mode power in appendix M1 for units with self-regulating crankcase heaters or heater systems in which the crankcase heater control is affected by the heater's heat. 82 FR 1426, 1438. Nevertheless, in the January 2023 RFI, DOE acknowledged that with more test procedure development time, an approach could potentially be developed that would allow for accurate projections of self-regulating crankcase heater energy use to be determined in reduced time and requested comment on this possibility. 88 FR 4091, 4103.

In the January 2023 RFI, DOE requested test data that would indicate if and how the 4-hour time delay (for compressors without sound blankets) and 8-hour time delay (for compressors with sound blankets) may be reduced for units with self-regulating crankcase heaters without compromising the accuracy of the off-mode power consumption measurement. 88 FR 4091, 4103. In response, Rheem commented that more study would be needed to understand the effects of delay reductions on both the accuracy of off-mode power consumption as well as on reliability of the compressor and crankcase heater. (Rheem, No. 12 at p. 7) No other stakeholders commented on this issue. Hence, DOE is proposing no changes to the 4- or 8-hour test duration for self-regulating crankcase heaters.

(d) Shoulder-Season Fan Power Consumption

In the January 2023 RFI, DOE requested comments on fan-only operation during the shoulder season, constant circulation controls, current use of constant circulation among CAC/HP products, the potential of increased future fan use (considering the transition to low-GWP refrigerants), and whether a need exists to account for constant circulation mode in the measurement of SEER2 and HSPF2. 88 FR 4091, 4101–4102. Additionally, DOE requested information on the typical fan power for constant circulation mode for blower-coil systems (or as a fraction of cooling or heating fan power), the percentage of people that use this mode and the associated hours per year on average the system would be in this mode, whether constant circulation mode is a default or user configurable

setting for these systems, whether the measurement of SEER2 and/or HSPF2 should take into consideration that a certain fraction of systems will use constant circulation mode rather than turn off the fan during the compressor off mode, and whether manufacturers could use constant circulation as part of their mitigation strategy for refrigerant leakage. (*Id.*)

In response, AHRI, Daikin, and Samsung all commented that constant circulation mode is a user configurable setting; and Samsung elaborated that the default constant circulation mode setting for its products is ''OFF.'' (AHRI, No. 14 at p. 11; Daikin, No. 16 at p. 7; Samsung, No. 11 at p. 2) AHRI and Daikin commented that only a small portion of consumers use constant circulation mode, citing the January 2023 RFI's reference to DOE's furnace fan efficiency rulemaking that suggests it is only used by 9 percent of consumers.[81] (AHRI, No. 14 at p. 11; Daikin, No. 16 at p. 7)

AHRI and Rheem commented that it is impossible to predict how widespread the use of constant circulation will be as a potential mitigation for A2L refrigerants. (AHRI, No. 14 at p. 11; Rheem No. 12 at pp. 5–6) Rheem explained that, for systems containing group A2L refrigerants and utilizing continuous circulation airflow as a mitigation strategy, the required circulation airflow rate is defined in safety standards as a function of system charge and refrigerant lower flammability limit. (Rheem No. 12 at pp. 5–6) Rheem noted that airflow rates (and associated blower motor power consumption) in continuous airflow mode for systems designed today—which contain group A1 refrigerants—are unlikely to be the same as the minimum circulation airflow rate defined in safety standards, and that, therefore, using data from systems sold today is unlikely to be representative of systems sold in the future. (*Id.*) Rheem asserted that it is difficult to predict whether manufacturers will redesign blower-coil systems to match the minimum circulation airflow as calculated from equations prescribed by safety standards, or choose an existing airflow tap that gives an airflow rate greater than the required minimum when utilizing continuous circulation airflow as the mitigation action. (*Id.*)

AHRI, Daikin, Rheem, and Samsung all were opposed to accounting for constant circulation mode in the test procedure and efficiency metrics for CAC/HPs, reasoning that, as described earlier, constant circulation airflow is utilized by only a small portion of all consumers and only occurs due to consumer selection. (AHRI, No. 14 at p. 12; Daikin, No. 16 at pp. 7–8; Rheem, No. 12 at p. 6; Samsung, No. 11 at p. 2) Conversely, the CA IOUs and NYSERDA both recommended that DOE consider addressing the energy consumption of fans in constant circulation mode for all products in either the CAC/HP test procedure or furnace fan test procedure. (CA IOUs, No. 10 at p. 4; NYSERDA, No. 9 at p. 12) To back its position, NYSERDA pointed to its evaluation of heat pump programs that found fan energy is not adequately accounted for in reported data and can be widely variable. (NYSERDA, No. 9 at p. 12) Further, NYSERDA suggested that, when a manufacturer's standard equipment settings include a continuous or intermittent fan-on mode of operation (for example, to sample the air temperature) as the default, constant fan-on energy should be incorporated in the standby power measurement, along with the bin-hour attribution of standby to SEER2 and HSPF2. (*Id.*)

As previously mentioned, AHRI and stakeholders, including DOE, considered several topics raised in the January 2023 RFI, including shoulder-season fan power consumption, when considering updated versions of industry standards. The information provided in the aforementioned comments was discussed in detail in the development of AHRI 1600–202X Draft. The draft industry test standards do not include constant circulation fan energy consumption in the efficiency metrics due to the use of this mode by the minority of consumers which are understood to select it, for systems for which the mode is user-selectable. However, for systems that require constant circulation at all times as a refrigerant leakage mitigation strategy, the constant circulation is considered as part of the standby and off mode energy use in the SCORE and SHORE metrics of AHRI 1600–202X Draft, and also in the cyclic degradation coefficient for both test standards. The AHRI 1600–202X Draft provisions that account for shoulder-season fan power consumption are detailed in section III.F.1.e of this NOPR.

(e) Accounting for Auxiliary Components' Power Consumption

The information provided by stakeholders in comments, summarized in the previous subsections, was discussed in detail in the development of AHRI 1600–202X Draft, which accounts for crankcase heater, base pan heater, and constant circulation fan energy consumption (as applicable) in the calculations of the new cooling and heating performance metrics, SCORE and SHORE. AHRI 1600–202X Draft introduces SCORE and SHORE as replacements for the current cooling and heating performance metrics, SEER2 and HSPF2, used to determine the measured efficiency of CAC/HPs. Unlike SEER2 and HSPF2, which DOE previously noted are only seasonal descriptors, these new metrics account for the standby and off-mode power consumption of auxiliary components, including those components discussed previously (*i.e.,* crankcase heaters and indoor fans utilizing constant-circulation) for both SCORE and SHORE; and, additionally, base pan heaters for SHORE.

AHRI 1600–202X Draft includes a new quantity, $E_{s,c}$ (measured in watt-hours), added to the denominator of the calculation for SCORE, meant to represent all auxiliary component energy usage during cooling mode (*i.e.,* during both cooling conditioning hours and cooling-season shoulder-season hours, as applicable). Outlined in section 11.2.1.4 of AHRI 1600–202X Draft, $E_{s,c}$ is the summation of each component's average power multiplied by each component's number of hours of standby operation during cooling mode, as follows:

$$E_{s,c} = (P_1 * N_1 + P_2 * N_2) + (P_{CCF} * N_{CCF})$$

Table 14 of AHRI 1600–202X Draft outlines instructions for determining each component's number of standby power operating hours in cooling mode (N_1 and N_2 for the crankcase heater and N_{CCF} for the constant circulation fan). In the case of crankcase heaters, calculations for N_1 and N_2 depend on the type of crankcase heater controls used by the CAC/HP system.

AHRI 1600–202X Draft also includes a new quantity, $E_{s,h}$ (also measured in watt-hours), added to the denominator of the calculation for SHORE, that is meant to represent all auxiliary component energy usage during heating mode (*i.e.,* during both heating conditioning hours and heating-season shoulder-season hours, as applicable). Outlined in section 11.2.1.4 of AHRI 1600–202X Draft, $E_{s,c}$ is the summation of each component's average power multiplied by each component's number of hours of standby operation during heating mode, as follows:

$$E_{s,h} = (P_1 * N_1 + P_2 * N_2) + (P_{BPH} * N_{BPH})$$

Table 16 of AHRI 1600–202X Draft outlines instructions for determining each component's number of standby power operating hours in heating mode (N_1 and N_2 for the crankcase heater,

[81] *See* 77 FR 28674, 28682–28683 for the survey data used to estimate this value in a furnace fan NOPR published on May 15, 2012.

N_{CCF} for the constant circulation fan, and N_{BPH} for the base pan heater). In the case of crankcase heaters, calculations for N_1 and N_2 depend on the type of crankcase heater controls used by the CAC/HP system. Similarly, the calculation of N_{BPH} depends on the type of base pan heater controls used by the system.

Appendix H of AHRI 1600–202X Draft outlines instructions for determining the average power (P_1 and P_2 for the crankcase heater, P_{CCF} for the constant circulation fan, and P_{BPH} for the base pan heater) of all auxiliary components considered in the calculations of either $E_{s,c}$ or $E_{s,h}$.

DOE surmises that the respective inclusions of $E_{s,c}$ and $E_{s,h}$ into the calculations of the new cooling and heating performance metrics, SCORE and SHORE, represent industry consensus regarding whether to reflect the power consumption of auxiliary components in the efficiency metrics for CAC/HPs. DOE has tentatively determined that inclusion of the energy consumed by auxiliary components in the efficiency metrics for CAC/HPs would result in more representative measures of efficiency. Therefore, DOE is proposing to incorporate by reference the new cooling and heating performance metrics, SCORE and SHORE, as included in AHRI 1600–202X Draft, and the associated provisions regarding the standby and off-mode power consumption of auxiliary components, in appendix M2.

2. Impact of Defrost on Performance

When operating in moderate to low outdoor ambient temperatures, the outdoor coil surface temperature of a HP is sufficiently low to freeze over, and frost collects on the coil. To combat the collection of ice on the outdoor coil, a HP must undergo a defrost cycle, where the HP temporarily switches to cooling mode operation. Temporarily switching to cooling mode operation enables a HP to transfer heat from the indoor coil to the outdoor coil, thus providing the heat needed to warm the coil and melt the frost. During defrost, different control strategies are applied to maintain comfort level inside the house. For example, the indoor fan may or may not be operated during defrost, and (if the indoor fan is operated) the auxiliary resistance heater may or may not be energized to warm the indoor air while the system is temporarily in defrost mode. Defrost initiation can be based on time (clock time or time of compressor operation), or the need for defrost can be determined based on temperature and pressure or other measurements that provide an indication of the need for defrost.[82] Currently, appendix M1 defines a demand-defrost control system as a system that defrosts the HP outdoor coil only when measuring a predetermined degradation of performance. When frequent defrost occurrences are not needed (*e.g.,* when there is insufficient moisture in the outdoor air to build up a significant frost layer on the outdoor coil), demand defrost can save energy by delaying defrost initiation. Defrost cycles are terminated when there is indication that defrost has been long enough for frost to be eliminated from the coil (*e.g.,* when a coil temperature sensor indicates the coil is well above 32°F).

(a) Demand Defrost Credit

For CAC/HPs equipped with demand defrost, appendix M1 includes a term called the demand defrost credit (''F_{def}'') in the HSPF2 calculation to provide nominal credit for HPs with a demand-defrost control system,[83] reflecting the relative improvement in heating mode efficiency due to use of demand defrost rather than defrosts with fixed periodicity. The credit equation has remained unchanged in its current form in the test procedure since at least January 22, 2001, when DOE published a NOPR regarding CAC/HP test procedures. 66 FR 6767. In the January 2023 RFI, based on test results of several CAC/HPs in various programs, DOE noted that it is aware of a range of defrost operation sequences and a range of approaches to defrost initiation for demand defrost. 88 FR 4091, 4104. Based on these observations, DOE acknowledged that the demand defrost credit may no longer accurately reflect the benefits of demand defrost. *Id.*

In the January 2023 RFI, DOE sought information on the operation of demand-defrost control systems, specifically any information that would indicate whether the demand-defrost credit outlined in the calculation in section 3.9.2 of appendix M1 is representative of the improvement in seasonal heating efficiency in field operation. 88 FR 4091, 4104. DOE also requested comment on whether any specific change in the credit equation could improve its accuracy. *Id.*

In response, AHRI, Daikin, and Rheem all commented that they would support an effort by stakeholders to establish a new demand defrost credit that incentivizes advanced defrost strategies and more accurately reflects the current state of defrost technology. (AHRI, No. 14 at p. 13; Daikin, No. 16 at pp. 9–10; Rheem, No. 12 at pp. 7–8) Similarly, the Joint Advocates encouraged DOE to provide a more sophisticated calculation of the credit, if a revised test procedure maintains the treatment of defrost separately (as a separate test). (Joint Advocates, No. 8 at pp. 3–4)

Daikin and the Joint Advocates commented that the current defrost credit is overly dependent on timing between defrosts and suggested that the current defrost credit calculation methodology should be modified to recognize, differentiate, and incentivize other advanced defrost strategies and their controls. (Daikin, No. 16 at pp. 9–10; Joint Advocates, No. 8 at pp. 3–4) Daikin specifically pointed out that appendix M1 currently only recognizes a 3-percent maximum credit during defrost for a defrost cycle of 91 minutes (even though modern equipment in some cases can go significantly longer than 91 minutes before performance degradation necessitates a defrost) and suggested that the current procedure be modified so that it no longer incentivizes the 91-minute cycle regardless of whether equipment needs to defrost at that time. (Daikin, No. 16 at pp. 9–10) The Joint Advocates noted that, in the definition of demand defrost control system, DOE acknowledges the different types of controls including parameters that vary with the amount of frost accumulated on the outdoor coil (*e.g.,* coil to air differential temperature, coil differential air pressure, outdoor fan power or current, or optical sensors) and suggested that these parameters be included in the calculation methodology of a new demand defrost credit. (Joint Advocates, No. 8 at pp. 3–4)

As previously mentioned, AHRI and other stakeholders, including DOE, discussed several issues raised in the January 2023 RFI, including the topic of the demand defrost credit, when considering updated versions of industry standards. The information provided in the aforementioned comments was discussed in detail in the development of AHRI 1600–202X Draft, which includes a simplified demand

[82] Some examples of parameters monitored for demand-defrost control systems are coil to air differential temperature, coil differential air pressure, outdoor fan power or current, optical sensors. Note that systems that vary defrost intervals according to outdoor dry-bulb temperature are not demand-defrost systems.

[83] The demand-defrost credit, first introduced in a March 14, 1988 rulemaking (53 FR 8304, 8319), is calculated by the following equation in section 3.9.2 of appendix M1: $F_{def} = 1 + 0.03[1 - \Delta\tau_{def} - 1.5/\Delta\tau_{max} - 1.5]$, where $\Delta\tau_{def}$ = time between defrost terminations (in hours) or 1.5, whichever is greater. $\Delta\tau_{def}$ is assigned a value of 6 if this limit is reached during a frost accumulation test and the heat pump has not completed a defrost cycle, and $\Delta\tau_{max}$ = maximum time between defrosts as allowed by the controls (in hours) or 12, whichever is less, as provided in the certification report.

defrost credit that uniformly applies a 3% increase to the SHORE rating for all HPs. As such, F_{def} no longer depends on the amount of time between defrost initiations (*e.g.,* T_{def} and T_{max} in appendix M1), and can be either one of two values: 1.03 (for systems equipped with a demand defrost control system) or 1 (for all other systems). DOE surmises that the simplified demand defrost credit in AHRI 1600–202X Draft represents industry consensus regarding improvements to the accuracy of the credit, incentives for more efficient defrost control strategies, and more accurate representations of modern defrost control technologies in the test procedure. DOE has tentatively determined that a simplified demand defrost credit would disincentivize unnecessary early defrosts (90 minutes after the termination of the prior defrost cycle), accurately represent defrost energy use while limiting test burden, and consequently allow for more advanced and efficient defrost control strategies. Therefore, DOE is proposing to incorporate by reference the simplified demand defrost credit in AHRI 1600–202X Draft, at appendix M2.

(b) Supplementary Heat Usage

Appendix M1 requires that HPs undergo a test at 35 °F dry-bulb temperature and 33 °F wet-bulb temperature, a condition for which frost accumulation is rapid, generally affecting performance before a 30-minute steady-state test can be completed. For this condition, the test procedure prescribes use of a transient test, including a frost accumulation period followed by defrost. Capacity and power input for the test are averaged for a full cycle of heating followed by defrost. At this condition, appendix M1 estimates the average capacity is at least 10 percent lower than it would be if there were no frost accumulation, while average power may be just slightly lower, thus reducing efficiency. At temperatures between 17 °F and 45 °F, the performance calculations prescribed in the test procedure call for representing capacity as a linear function of temperature based on the tests conducted at 17 °F and 35 °F—likewise for power input. Hence, the frost/defrost impact is built into the HSPF2 calculation for temperatures in this range. The DOE test procedure requires use of the 35 °F test for single-stage and two-stage HPs for all capacity levels. However, for variable speed HPs, the test procedure requires the defrost test be conducted only at intermediate compressor speed, and performance is estimated using default degradation factors at full capacity (*see* section 3.6.4.1.c of appendix M1).

In the January 2023 RFI, DOE noted that it has observed variations in testing among HP models regarding defrost control (*e.g.,* time durations of the defrost can vary significantly for different models, and the indoor unit fan shuts off during defrost for some units but not all). 88 FR 4091, 4104. In addition, as part of testing systems with electric resistance heaters for the DOE CCHP Tech Challenge, DOE noted that it has observed that resistance heater operation during defrost can vary significantly for different models. (*Id.*) DOE acknowledged that this varying behavior clearly affects energy use, and, while some aspects of resistance heater operation may be captured by the current appendix M1 test procedure, others may not be.

As a result, in the January 2023 RFI, DOE requested information regarding defrost impact on heating capacity and power input over a range of temperatures to inform evaluation of whether the approach used in the DOE test procedure to account for this impact is accurate or whether it could be improved.

In response, Daikin commented that it believes the current appendix M1 test conditions represent the worst-case scenario and adequately capture performance during frosting and defrosting operation. (Daikin, No. 16 at pp. 9–10) As such, Daikin asserted that additional test points would provide little benefit. (*Id.*) Similarly, neither AHRI nor Rheem had any concerns with the current testing approach. (AHRI, No. 14 at p. 13; Rheem, No. 12 at p. 8)

However, Daikin, the Joint Advocates, and NEEA all suggested that DOE somehow include auxiliary resistance heat during defrost as part of the defrost test, claiming it would be more representative to include this power. (Daikin, No. 16 at p. 12; Joint Advocates, No. 8 at p. 3; NEEA, No. 13 at p. 8) Currently, the appendix M1 test procedure specifies that electric heat is not to be powered during the defrost test, regardless of whether a unit may do so in the field. To try and estimate the change in efficiency that comes with including auxiliary resistance heat, the Joint Advocates cited a recent Purdue study of a 3-ton, single-stage heat pump, which calculated a COP at 34 °F that was 10-percent lower when the auxiliary heat was allowed to operate in defrost.[84] (Joint Advocates, No. 8 at p. 3) Acknowledging that many test facilities are not designed to handle the power required for auxiliary heat operation, Daikin suggested that power be added to the defrost test energy consumption and capacity as a calculation only, based on the maximum allowable power for a given HP system. (Daikin, No. 16 at p. 12)

NYSERDA and the Joint Advocates both noted that as a load-based test, SPE07 would inherently address defrost impacts, including power input and capacity loss, and require no separate test. (Joint Advocates, No. 8 at pp. 3–4; NYSERDA, No. 9 at pp. 10–11)

As previously mentioned, AHRI and other stakeholders, including DOE, discussed several topics raised in the January 2023 RFI, including the topic of accounting for supplementary heat usage (*e.g.,* auxiliary resistance heat) in the CAC/HP efficiency metrics, when considering updated versions of industry standards. The information provided in the aforementioned comments was discussed in detail in the development of AHRI 1600–202X Draft, which accounts for use of supplementary heat during defrost. The AHRI 1600–202X Draft approach reduces the efficiency ratings of such systems, depending on: (1) whether the HP uses what is defined as defrost heat mode; (2) whether the HP meets what is defined as the lockout limitation criteria; and (3) the time period for which the HP operates in what is defined as defrost overrun mode. The definitions for defrost heat mode, lockout limitation, and defrost overrun mode in AHRI 1600–202X Draft are shown below.

Defrost Heat Mode means a mode of operation in which an indoor heating source controlled by any component of the rated combination (*e.g.,* by the heat pump, heat pump controls, blower controls, or thermostat) operates for any period of time while the system is defrosting. Heat pump systems that have the ability to operate the indoor blower during defrost, whether or not that ability is the manufacturer default, are considered to have a *Defrost Heat Mode.*

Defrost Overrun Mode means a mode of operation in which a rated individual combination that has been operating in a *Defrost Heat Mode,* continues to operate for a period of time following the termination of a defrost. In order to qualify as having a *Defrost Overrun Mode,* rated individual combinations must first have a *Defrost Heat Mode.*

Lockout Limitation means rated individual combinations that lock out the operation of all non-heat pump indoor heating sources under the control of the rated individual

[84] *See docs.lib.purdue.edu/cgi/viewcontent.cgi?article=3475&context=iracc* at p. 6. The 34 °F outdoor ambient test condition is taken from EXP07.

combination during defrost do not have a *Defrost Heat Mode.* Locking out means preventing those heating sources from operating in all cases, with no configuration option to change this behavior.

AHRI 1600–202X Draft introduces two new debits, multiplied to the new heating metric, SHORE, in the same manner as the demand defrost credit, to penalize the efficiency ratings of HPs that use defrost heat mode (unless they meet the lockout limitation criteria) or spend a period of time greater than or equal to 60 seconds in defrost overrun mode. One such debit is the defrost heat debit (''F_H''), which is meant to reflect the reduction in efficiency experienced by HPs that use defrost heat mode and can be either one of two values: 0.98 (for systems with a defrost heat mode) or 1 (for systems that meet the lockout limitation criteria). The second debit is the defrost overrun debit (''F_O''), which is meant to reflect the reduction in efficiency experienced by HPs that spend longer time periods in defrost overrun mode and can be either one of two values: 0.98 (for systems with a defrost overrun mode greater than or equal to 60 seconds) or 1.00 (for systems with a defrost overrun mode less than 60 seconds, or systems that meet the lockout limitation criteria).

DOE surmises that the AHRI 1600–202X Draft's introductions of the defrost heat debit, the defrost overrun debit, and the associated definitions for defrost heat mode, lockout limitation, and defrost overrun mode represent industry consensus regarding whether and how to include the additional power consumption required by supplementary heat (*e.g.,* auxiliary resistance heat) in the defrost test. DOE has tentatively determined that these provisions result in more representative CAC/HP efficiencies for models with supplementary heat during defrost. Therefore, DOE is proposing to incorporate by reference at appendix M2 the defrost heat debit, the defrost overrun debit, and the associated definitions for defrost heat mode, lockout limitation, and defrost overrun mode in AHRI 1600–202X Draft.

3. Updates to Building Load Lines and Temperature Bin Hours

In the current CAC/HP test procedure at appendix M1, the cooling efficiency metric, SEER2, is calculated by evaluating the ratio of the heating removed from the conditioned space to the energy use of the refrigeration cycle during the cooling season. For CHPs, the heating efficiency metric, HSPF2, is calculated by evaluating the ratio of the heating provided to the conditioned space to the space energy usage of both the CHP unit (reverse refrigeration cycle) and the resistive heat component, during the heating season. For the evaluation of SEER2 and HSPF2, the respective ratios are summed over a temperature range, which is split into 5-degree ''bins,'' and an average temperature and fractional hours are assigned to each bin, denoted by *n(j)/N.* The cooling season fractional hours, used in the evaluation of SEER2, are set forth at Table 19 of appendix M1. The heating season fractional hours, used in the evaluation of HSPF2, are set forth at Table 20 of appendix M1. The HSPF2 rating is calculated using the fractional hours particular to Region IV. The amount of cooling and/or heating delivered are driven by the building cooling and heating loads, $BL(T_j)$.[85] For the current test procedure, the building cooling and heating loads are both proportional to the nominal cooling capacity at 95 °F outdoor temperature, $\dot{Q}_c$(95 °F), except for heating-only heat pumps, for which the heating load is directly proportional to the nominal heating capacity at 47 °F outdoor temperature, $\dot{Q}_h$(47 °F).

In response to the January 2023 RFI, NYSERDA encouraged DOE to reevaluate the fractional cooling bin hours used for calculating SEER2. (NYSERDA, No. 9 at pp. 9–10) NYSERDA pointed out that these fractional cooling bin hours were originally developed in 1978 specifically for units with a two-speed compressor and units equipped with two compressors. (*Id.*) NYSERDA suggested that these hours should be recalculated using more recent Typical Meteorological Year (''TMY'') data, and also consider the improvements in CAC/HP technology since 1978. (*Id.* at p. 10)

As previously mentioned, AHRI 1600–202X Draft includes new cooling and heating metrics for namely SCORE and SHORE. These new metrics use total hours instead of fractional hours. This change is consistent with the recent approach of having metrics that represent total conditioning delivered divided by all power consumed. Total hours are split into conditioning hours and shoulder hours—conditioning hours are hours when conditioning (cooling/heating) is required and shoulder hours are hours when conditioning (cooling/heating) is not required (*i.e.,* there is no conditioning load). For the cooling season, the total hours are split into cooling conditioning hours and cooling season shoulder hours. For the heating season, the total hours are split into heating conditioning hours and heating season shoulder hours. The cooling conditioning hours and cooling season shoulder hours for each bin are listed in Table 13 of AHRI 1600–202X Draft, and the heating conditioning hours and heating season shoulder hours for each bin are listed in Table 15 of AHRI 1600–202X Draft.

The total hours for the cooling and heating seasons were calculated using TMYx:2007–2021 data (''TMYx''), which is a specific set of weather data from years 2007 to 2021. Because SCORE and SHORE are intended to be national efficiency standards, the total hours for each season were population-weighted. Multiple cities were selected, based on their population, from each climate zone specified in ASHRAE 169–2021,[86] for capturing the variations in climate along those zones. To determine the appropriate split between conditioning hours (*i.e.,* when cooling/heating is required) and shoulder hours (*i.e.,* when cooling/heating is not required), Pacific Northwest National Laboratory (''PNNL'') performed a series of building load analyses using EnergyPlus version 9.6 on a prototype single-family detached house based on the 2009 IECC code, located in representative cities in ASHRAE climate zones 1–8. The inputs for the EnergyPlus simulations were selected to largely mirror those that had been previously used in informing the January 2017 Final Rule, but with appropriate updates to the weather data and the IECC code.[87] The underlying weather data was updated to TMYx and the IECC building code was updated to the 2009 version. The data from each individual EnergyPlus simulation output was binned and yielded the cooling conditioning hours, cooling season shoulder hours, heating conditioning hours, and heating season shoulder hours for each climate zone, which were then population-weighted to arrive at the national numbers in Table 13 and Table 15 of AHRI 1600–202X Draft. Additionally, for CAC/HPs

[85] The building cooling load and building heating load are calculated by Equations 4.1–2, and 4.2–2, respectively, in appendix M1.

[86] ASHRAE 169–2021 ''Climatic Data for Building Design Standards'' provides a variety of climatic information used mainly the design, planning and sizing of buildings' energy systems and equipment. Available for purchase at *www.ashrae.org/technical-resources/bookstore/weather-data-center#:~:text=Standard%20169%2D2021%2C%20Climatic%20Data,the%202021%20ASHRAE%20Handbook%E2%80%94Fundamentals.*

[87] For the January 2017 Final Rule, the building load analysis done by ORNL using EnergyPlus is summarized in the following report: ORNL, Rice, C. Keith, Bo Shen, and Som S. Shrestha, 2015. An Analysis of Representative Heating Load Lines for Residential HSPF Ratings, ORNL/TM–2015/281, July. (Docket No. EERE–2009–BT–TP–0004–0046).

located in cold climates, Table 15 of AHRI 1600–202X Draft also includes the ''Cold Climate Average'' heating conditioning hours and heating shoulder hours. These were calculated by a population-weighted average of the data from EnergyPlus simulations for the colder climate ASHRAE zones 5–8.

Regarding updates to the building load lines, the PNNL EnergyPlus simulations also yielded the average cooling and average heating loads for each climate zone, binned by temperature intervals of 5 °F. The results obtained were largely consistent with the building load lines ($BL(T_j)$) in the current appendix M1, barring the minor flattening of the building load near the zero-load points. As such, the equations used for calculating the building loads were 'split' into two sections in AHRI 1600–202X Draft. The cooling building load line for outdoor temperatures at and above 72.5 °F was maintained consistent with current appendix M1, but with one change—requiring that the multiplier 'V' in the cooling building load line apply to all variable-capacity compressor systems instead of just variable-capacity heat pumps.

For outdoor temperatures above 72.5 °F, the cooling building load line was modified, given by:

$$BL(t_j) = \frac{\{tj - 61\}}{\{72.5 - 61\}} \cdot BL(72.5)$$

Where *BL*(47.5) is the cooling building load at 72.5 °F.

Similarly, the heating building load line for outdoor temperatures at and below 47.5 °F was maintained consistent with current appendix M1, but with one change—requiring that the slope (adjustment) factor,C_x, be set to 1.07 for variable-capacity compressor systems, and 1.15 otherwise, regardless of climate zone.

For outdoor temperatures above 47.5 °F, the heating building load line was modified, given by:

$$BL(t_j) = \frac{\{59 - t_j\}}{\{59 - 47.5\}} \cdot BL(47.5)$$

Where *BL*(47.5) is the heating building load at 72.5 °F.

DOE surmises that the switch from fractional hours to total hours, the associated values of the conditioning hours and shoulder hours, and changes in the building load line equations represent industry consensus for calculations of the new cooling and heating performance metrics, SCORE and SHORE. DOE has tentatively determined that this approach best represents CAC/HP operation over a representative period of use. Therefore, DOE is proposing to incorporate by reference the new cooling conditioning hours, cooling season shoulder hours, heating conditioning hours, heating season shoulder hours, and the updated building load line equations in the AHRI 1600–202X Draft, at appendix M2. DOE is also clarifying that representations of SHORE made using the 'Cold Climate Average' heating conditioning hours and shoulder season hours in Table 15 of AHRI 1600–202X Draft are optional.

4. Default Fan Power Coefficients for Coil-Only Systems

Coil-only air conditioners are matched split systems consisting of a condensing unit and indoor coil that are distributed in commerce without an indoor blower or separate designated air mover. Such systems installed in the field rely on a separately installed furnace or a modular blower for indoor air movement. Because coil-only CAC/HPs do not include their own indoor fan to circulate air, the DOE test procedures prescribe equations that are used to calculate the assumed (*i.e.,* ''default'') power input and heat output of an average furnace fan with which the test procedure assumes the indoor coil is paired in a field installation. In each equation, the measured airflow rate (in cubic feet per minute of standard air (''scfm'')) is multiplied by a defined coefficient (expressed in Watts (''W'') per 1000 scfm (''W/1000 scfm'') for fan power, and Btu/h per 1000 scfm (''Btu/h/1000 scfm'') for fan heat), hereafter referred to as the ''default fan power coefficient'' and ''default fan heat coefficient.'' The resulting fan power input value is added to the electrical power consumption measured during testing. The resulting fan heat output value is subtracted from the measured cooling capacity of the CAC/HP for cooling mode tests and added to the measured heating capacity for heating mode tests.

In appendix M1, separate fan power and fan heat equations are provided for different types of coil-only systems (*e.g.,* the equations for mobile home or space-constrained are different than for ''conventional'' non-mobile home and non-space-constrained, and the equations for single-stage are different than for two-stage and variable speed).[88] *See, e.g.,* appendix M1, section 3.3. For single-stage coil-only units installed in mobile homes and for single-stage space-constrained systems, appendix M1 defines a default fan power coefficient of 406 W/1000 scfm and a default fan heat coefficient of 1385 Btu/h/1000 scfm. *See, e.g.,* appendix M1, section 3.3.d. For single-stage coil-only units installed in ''conventional'' (*i.e.,* non-mobile-home and non-space-constrained) systems, appendix M1 defines a default fan power coefficient of 441 W/1000 scfm and a default fan heat coefficient of 1505 Btu/h/1000 scfm. *See, e.g.,* appendix M1, section 3.3.e.

For two-stage and variable speed coil-only systems, appendix M1 defines equations to interpolate different default fan power coefficients and default fan heat coefficients for the full-load and part-load tests, depending on the air volume rate used for each test expressed as a percentage of the cooling full-load air volume rate (''%FLAVR''). *See, e.g.,* appendix M1, section 3.3, equations for $DFPC_{MHSC}$ and $DFPC_C$. Appendix M1 interpolates the default fan power coefficient for two-stage and variable speed coil-only units installed in mobile homes and for two-stage and variable speed space-constrained coil-only systems (''$DFPC_{MHSC}$'') using assumptions for full-load default fan power at 406 W (*i.e.,* the same as for single-stage systems) and a lower-load default fan power at a reduced air volume rate of 75 percent, at 308 W. For ''conventional'' non-mobile-home and non-space-constrained two-stage and variable speed systems, appendix M1 interpolates the default fan power coefficient (''$DFPC_C$'') using assumptions for full-load default fan power at 441 W (*i.e.,* the same as for single-stage systems) and a lower-load default fan power at a reduced air volume rate of 75 percent, at 335 W. The default fan power values used in the determination of the default fan power coefficients were a result of empirical analysis presented by DOE in the October 2022 Final Rule. (*See* 87 FR 64550, 64555–64559).

As previously mentioned, AHRI and other stakeholders, including DOE, considered several topics, including the topic of default fan power coefficients for coil-only systems, when developing updated versions of industry standards. AHRI 1600–202X Draft updates the default fan power values used in each interpolation to better reflect the fan power values used by coil-only systems today (on average) and changes the equations for default fan power

[88] The different default fan power and default fan heat coefficients for mobile-home and space-constrained systems as compared to conventional systems reflect the lower duct pressure drop expected for such systems in field operation—the lower values are consistent with the lower ESP levels required in testing of blower-coil systems intended for mobile home and spaced-constrained applications (*see* Table 4 of appendix M1).

coefficients to use lower-load default fan powers at a reduced air volume rate of 65 percent, rather than 75 percent as in appendix M1. For space-constrained coil-only systems, the AHRI 1600–202X Draft uses a full-load default fan power of 293 W and a lower-load default fan power of 135 W in the default fan power coefficient interpolation. For non-space-constrained coil-only systems, AHRI 1600–202X Draft uses a full-load default fan power of 346 W and a lower-load default fan power of 159 W. All default fan powers are lower than those used in the calculation of $DFPC_{MHSC}$ and $DFPC_C$ in appendix M1. DOE surmises that the new equations for default fan power coefficients and default fan heat coefficients (and their reduced full-load default fan powers and their reduced lower-load default fan powers at a reduced air volume rate of 65 percent) in AHRI 1600–202X Draft represent industry consensus regarding the assumed power input and heat output of an average furnace fan or modular blower with which the test procedure assumes the indoor coil is pared in a field installation. DOE has tentatively determined that the reduced full-load and low-load default fan powers more accurately reflect the average design of the current installed base for blowers paired with coil-only CAC/HP installations, which increasingly use more efficient fan motors (with lower wattages). DOE has also tentatively determined that the reduced air volume rate more accurately reflects the average low-load air volume rate of the current installed base for blowers paired with coil-only CAC/HP installations. Therefore, DOE is proposing to incorporate by reference the default fan power coefficient equations and default fan heat coefficient equations, and associated default fan powers used to interpolate such coefficients, in AHRI 1600–202X Draft, at appendix M2.

5. Indoor Ambient Test Conditions for Cooling Mode Tests

Currently, appendix M1 prescribes test conditions for CAC/HPs in Tables 5, 6, 7, and 8 that require all cooling mode tests to be performed under air entering indoor unit temperatures of 80 °F (dry-bulb temperature)/67 °F (wet-bulb temperature), with some wet-bulb temperature exceptions.

In response to the January 2023 RFI, DOE received several comments regarding these indoor ambient test conditions. As mentioned previously in this NOPR, the Joint Advocates encouraged DOE to choose more representative indoor air temperatures for the cooling mode tests. (Joint Advocates, No. 8 at p. 3) Specifically, the Joint Advocates referred to an ACEEE paper [89] that suggests indoor temperatures of 75 °F/63 °F would be more representative than the 80 °F/67 °F conditions currently used in appendix M1. (*Id.*) The Joint Advocates also referred to recommendation 4 of the 2022 ASRAC CUAC and CUHP WG TP term sheet, which recommends return air temperature (''RAT'') test conditions for cooling at 77 °F/64 °F, not 80 °F/67 °F, to calculate seasonal performance metrics. (*Id.*) Similarly, NYSERDA also recommended that DOE consider revising the air entering indoor unit temperature conditions in the cooling mode tests, asserting that the conditions are not representative of actual setpoints in the field, per 2020 RECS data.[90] (NYSERDA, No. 9 at p. 9)

In its comments regarding the comparison of appendix M1 test conditions to those test conditions used by SPE07, Daikin pointed out that changing the indoor dry-bulb and wet-bulb temperature conditions would significantly alter the numerical value of resultant efficiency metrics. (Daikin, No. 16 at p. 5) Specifically, Daikin estimated that changing the indoor ambient test conditions from 80 °F/67 °F to 75 °F/63 °F alone would result in an approximate 9-percent reduction in capacity (and therefore efficiency), although Daikin could not share its data to back this estimate. (*Id.*) If the indoor ambient test conditions were to change, Daikin stated that the numerical shift should not affect the ranking order of CAC/HPs by measured efficiencies. (*Id.*) Daikin also noted that requiring additional testing at different test conditions would increase time burden, costs, and trouble for manufacturers. (*Id.*)

The information provided in the aforementioned comments was discussed in detail in the development of the AHRI 1600–202X Draft, which maintained the existing indoor ambient test conditions for cooling tests. DOE surmises that this absence of change tentatively represents industry consensus regarding whether the existing 80 °F/67 °F indoor ambient test conditions require amendments at this time. DOE has tentatively determined that the potential benefits of such a change would not outweigh the resulting consumer confusion and oversizing issues stemming from a change to the nominal ratings of systems. Therefore, DOE is proposing no change to the current indoor ambient test conditions for the cooling mode tests.

6. Air Flow Limits To Address Inadequate Dehumidification

During the development of AHRI 1600–202X Draft, AHRI and other stakeholders, including DOE, considered a variety of topics regarding CAC/HPs, including topics that were not explicitly raised by issues presented in the January 2023 RFI. Among those topics was how to address issues relating to the dehumidification inadequacy of some CAC/HPs. Some CAC/HPs have sensible heat ratios (''SHRs'') too high to meet consumer needs for dehumidification, especially in hot and warm, humid climates.

To ensure that CAC/HPs ratings account for adequate dehumidification in these climates, the AHRI 1600–202X Draft establishes new airflow limits for the cooling mode tests to avoid high SHRs. Specifically, section 6.1.5.2 of the AHRI 1600–202X Draft sets a maximum airflow limit at 37.5 scfm per 1000 Btu/h (*i.e.,* 450 cfm per ton of capacity) for cooling full airflow. Additionally, section 6.1.5.3 of the AHRI 1600–202X Draft sets a maximum airflow limit at 50 scfm per 1000 Btu/h (*i.e.,* 600 cfm per ton of capacity) for cooling low airflow. Should the cooling full airflow or cooling low airflow specified by the manufacturer exceed these limits, the AHRI 1600–202X Draft requires that airflows be reduced to meet these limits for testing.

DOE surmises that the addition and selection of specific cooling airflow limits in the AHRI 1600–202X Draft represent industry consensus regarding the issue of inadequate dehumidification. DOE has tentatively determined that such airflow limits are appropriate to ensure that CAC/HPs provide adequate dehumidification during cooling mode operation. Therefore, DOE is proposing to incorporate by reference the cooling full airflow and cooling low airflow limits specified in the AHRI 1600–202X Draft, at appendix M2.

H. General Comments Received in Response to the January 2023 RFI

In response to the January 2023 RFI, DOE received several general comments not specific to any one test procedure provision. This section discusses those general comments received.

Both AHRI and NCP commented that the requirement to test according to appendix M1 (effective January 1, 2023), specifically the change to SEER2 and HSPF2 metrics, caused considerable confusion in the marketplace. (AHRI, No. 14 at p. 4; NCP, No. 7 at p. 2) As

[89] *See www.aceee.org/files/proceedings/2006/data/papers/SS06_Panel1_Paper24.pdf.*

[90] *See www.eia.gov/consumption/residential/data/2020/hc/pdf/HC%207.1.pdf.*

a result of the metrics change (and lower values for efficiency for SEER2 and HSPF2), AHRI and NCP explained that they and other manufacturers worked together to develop educational resources for dealers, contractors, code officials, and end-users in an effort to quell confusion. (*Id.*) However, AHRI stated that distributing such resources was difficult considering the large number of contractors and installers in jurisdictions across the nation. (*Id.*) Both AHRI and NCP commented that the burden associated with the previous metrics change to SEER2 and HSPF2 was not well accounted for in the last test procedure rulemaking. (*Id.*) Subsequently, NCP stated that DOE should allow time to measure the overall impact of the new appendix M1 ratings and assess any actual benefit before undertaking additional steps to amend the procedure in this test procedure rulemaking. (NCP, No. 7 at p. 2)

As noted earlier, DOE is proposing to incorporate by reference industry standards at appendix M1 and appendix M2, which were developed with the broad consensus of several stakeholders, including AHRI and NCP. It is DOE's hope that incorporating each industry standard in full as the basis for each respective appendix would enable DOE to limit manufacturer burden that would have otherwise arisen solely due to certifying to a standalone Federal test procedure. DOE has tentatively determined that the revisions proposed at appendix M1 would not result in changes in the SEER2 and HSPF2 metrics, and notes that use of appendix M2 would not be required until the compliance date of any amended standards denominated in terms of the new metrics, SCORE and SHORE. Additionally, DOE has assessed the test procedure costs and impacts in section III.M of this NOPR and has provided an opportunity to comment.

Lennox stated that DOE should fully consider the impacts of transitioning to lower GWP refrigerants as part of the test procedure rulemaking process. (Lennox, No. 6 at p. 2) Lennox commented that HVACR manufactures will be investing millions of dollars in product development and capital investment to facilitate a transition across the entire HVACR product portfolio of residential and commercial equipment and that these impacts must be considered in this test procedure rulemaking. (*Id.*)

DOE notes that Lennox did not identify any specific impacts related to transitioning to low GWP refrigerants. As discussed in section III.F.5, DOE has considered that with the use of low GWP refrigerants, particularly A2L refrigerants, a subsequent need may exist for the constant circulation of air or circulation based on leak detection to accommodate the refrigerant leak detection and mitigation strategies in CAC/HP product design. Both the AHRI 210/240–202X Draft and AHRI 1600–202X Draft include provisions for such systems, which DOE is incorporating by reference at appendix M1 and appendix M2, respectively. Lennox was involved in the development of these industry standards and DOE surmises that Lennox's concerns pertaining to impacts of lower GWP refrigerants have been appropriately addressed.

Lennox also stated that DOE should exercise caution as it proceeds with test procedure amendments for CAC/HP products to ensure the impacts and timing of test procedure amendments are fully considered, particularly so that manufacturers may fully evaluate any test procedure impacts before DOE assesses potentially amending energy conservation standards. (Lennox, No. 6 at p. 2)

In response to Lennox, DOE notes that both test procedures and energy conservation standards actions are subject to the requirements of EPCA. As discussed, EPCA states that the Secretary shall review test procedures for all covered products, including CAC/HPs, at least once every 7 years. (*see* 42 U.S.C. 6293(b)(1)(a)) The most recent CAC/HP test procedure rulemaking completed in satisfaction of EPCA's 7-year review requirement concluded with the January 2017 Final Rule. (*See* 82 FR 1426). Similarly, EPCA also requires that, not later than 6 years after the issuance of any final rule establishing or amending a standard, DOE evaluate the energy conservation standards for each type of covered product, including CAC/HPs, and publish either a notification of determination that the standards do not need to be amended, or a NOPR that includes new proposed energy conservation standards (proceeding to a final rule, as appropriate). (*See* 42 U.S.C. 6295(m)(1)) The most recent CAC/HP energy conservation standards rulemaking completed in satisfaction of EPCA's 6-year review requirement concluded with a direct final rule published on January 6, 2017 (''January 2017 ECS DFR''). (*See* 82 FR 1786). As noted, revisions proposed at appendix M1 would not result in changes in the SEER2 and HSPF2 metrics, and use of appendix M2 would not be required until the compliance date of any amended standards denominated in terms of the new metrics, SCORE and SHORE. DOE has tentatively determined that this proposed test procedure structure would provide sufficient time to assess new metrics when considering any future amended energy conservation standards.

While Lennox stated it supports test procedure changes to improve the representativeness of the CAC/HP test procedures, it also emphasized that such changes must not be unduly burdensome. (Lennox, No. 6 at p. 4) Similarly, NCP stated that DOE should avoid amendments to the test procedure that increase burden and noted that EPCA requires test procedures to not be unduly burdensome. (NCP, No. 7 at p. 2) Specifically, NCP stated that DOE should avoid amendments to the test procedure that increase burden for space-constrained AC and HP products, as it has found no significant benefits to be attained by test procedure changes to this type of product at this time. (*Id.*)

As discussed previously, EPCA requires test procedures proposed by DOE not be unduly burdensome to conduct. (*See* 42 U.S.C. 6293(b)(3)) DOE discusses the estimated costs and impact of the proposed test procedures at appendix M1 and appendix M2 in section III.M of this NOPR. As noted earlier, DOE is proposing to incorporate by reference industry standards at appendix M1 and appendix M2 that were developed with the broad consensus of several stakeholders, including Lennox and NCP. DOE has tentatively determined that incorporating each industry standard in full as the basis for each respective appendix would limit manufacturer burden.

AHRI requested that DOE parse test procedure changes into separate groupings, so stakeholders can understand those changes that would substantively impact the ratings and, if possible, the extent of their impact. (AHRI, No. 14 at p. 4)

In response, DOE notes that it has categorized the proposed test procedures by topic and timing of changes (*i.e.,* near-term changes at appendix M1 versus long-term changes at appendix M2) to assist in manufacturers' understandings of the changes themselves and the impacts they may pose.

The Joint Advocates encouraged DOE to consider additional reporting requirements in a test procedure rulemaking. (Joint Advocates, No. 8 at p. 4) Specifically, the Joint Advocates asserted that the ability for various stakeholders to calculate performance in any climate will likely be very important for the adoption of heat pumps in coming years. (*Id.*) Subsequently, the Joint Advocates

encouraged DOE to engage stakeholders to determine which additional performance reporting requirements would be beneficial (*e.g.,* capacity maintenance or COP at various temperatures) in a test procedure rulemaking. (*Id.*)

In response, DOE notes that it will consider certification requirements for CAC/HPs, including additional reporting requirements mentioned by the Joint Advocates, in a separate rulemaking for certification, compliance, and enforcement.

NYSERDA recommended that DOE consider approaches in the test procedure that address both demand response-enabled and thermal storage performance features of CAC/HPs. (NYSERDA, No. 9 at p. 14) To highlight the potential opportunities for load curtailment using demand response, NYSERDA stated that it evaluated outdoor temperatures greater than or equal to 95 °F for certain U.S.-based cities. (NYSERDA, No. 9 at p. 14) NYSERDA stated that it then developed charge and discharge pattern estimates using renewable portfolio standards (''RPS'') as a pathway to generation while relying on the energy storage perspectives offered in a California Independent System Operator Corporation (''CAISO'') report on California and Europe.[91] (*Id.*) NYSERDA stated that these estimates are summarized in Figure 1 of NYSERDA's response to the January 2023 RFI. (*Id.*) NYSERDA commented that several high outdoor temperatures within Figure 1 fall within the charge zone associated with lower-price periods and high generation and contended that the small percentage of outdoor temperatures within the discharge zone (*i.e.,* higher price periods with peak demand) could be managed using the general curtailment and critical curtailment approaches specified in AHRI Standard 1380–2019. (*Id.*)

Additionally, NYSERDA noted that specifications issued by EPA and the Consortium for Energy Efficiency (''CEE'') prescribe connected criteria for demand response-enabled products, and that energy efficiency program administrators may consider offering incentives on connected criteria to strategically manage peak load outside of solely focusing on performance metrics such as SEER2, HSPF2, and EER2. (NYSERDA, No. 9 at p. 14) NYSERDA recommended that DOE account for such demand response-enabled features in the revised test procedure, for example, by down-weighting or eliminating the bin hours from the SEER2 rating above a typical curtailment threshold. (*Id.*) NYSERDA stated that this could be provided as a secondary metric so that users who choose not to participate in demand-response programs would still have access to the ''normal'' SEER2 rating for comparison. (*Id.*)

Neither AHRI 210/240–202X Draft nor AHRI 1600–202X Draft include any provisions regarding demand response-enabled products. In the absence of discussion or changes to the AHRI test procedures, DOE surmises that no changes need to be made regarding demand response-enabled CAC/HP products in the test procedures at this time. Therefore, DOE is proposing no provisions to address demand response-enabled CAC/HP products in the test procedures at either appendix M1 or appendix M2. DOE will continue to evaluate demand response functions in CAC/HPs and consider whether such functions should be accounted for in a future DOE test procedure. While DOE is not proposing changes to the Federal test procedures, DOE does note that the ENERGY STAR Spec V6.1 includes requirements for demand response capability and provides a means for product differentiation.

NYSERDA also commented that it has been working with heat pump technologies that incorporate thermal storage,[92] and suggested that this technology would fit under DOE's CAC/HP test procedure rulemaking. (NYSERDA, No. 9 at pp. 14–15) NYSERDA recommended that DOE consider if this technology may make sense to be a standalone product category or otherwise consider the potential growth of this technology and how it would fit into the scope of CAC/HPs. (*Id.*)

As previously mentioned, AHRI and other stakeholders, including DOE, considered a variety of topics regarding CAC/HPs. However, the topic of heat pump technologies that incorporate thermal storage was not brought up as a topic for discussion, and neither AHRI 210/240–202X Draft nor AHRI 1600–202X Draft include any provisions regarding such technologies. Additionally, DOE has tentatively determined that heat pumps with thermal storage are a niche application, and DOE currently does not have enough information to include test provisions for such systems within CAC/HP test procedure. DOE also has not received any petitions for test procedure waivers to date that would address this technology. In the absence of discussion or changes to the AHRI test procedures, DOE has tentatively determined that no provisions are currently necessary regarding heat pump technologies that incorporate thermal storage in the test procedures at either appendix M1 or appendix M2. However, DOE may consider the topic of heat pump technologies that incorporate thermal storage in a future rulemaking.

I. Represented Values

In the following sections, DOE discusses requirements regarding represented values. To the extent that DOE is proposing changes to the requirements specified in 10 CFR 429 regarding representations of CAC/HPs, such amendments to 10 CFR part 429, if made final, would be required starting 180 days after publication in the **Federal Register** of the test procedure final rule. Prior to 180 days after publication in the **Federal Register** of the test procedure final rule, the current requirements would apply. However, manufacturers would be permitted to choose between using the current or new requirements for a period between 30 days and 180 days after publication in the **Federal Register** of the test procedure final rule.

1. Calculating Represented Values for the Federal Trade Commission

As described in a final rule regarding EnergyGuide labels published on October 12, 2022, the Federal Trade Commission (''FTC'') is responsible for periodical updates to energy labeling for major home appliances and other consumer products, including CAC/HPs, to help consumers compare competing models. 87 FR 61465, 61466. Among other disclosures, EnergyGuide labels for CAC/HPs include estimated annual energy costs for both cooling and heating, which are based on the represented values for each basic model's efficiencies (SEER2 and HSPF2, as applicable) and cooling capacities and estimates for cooling load hours (''CLH'') and heating load hours (''HLH'') in a year. Currently, the FTC uses 1,000 and 1,572 hours as estimates for CLH and HLH, respectively, for all ratings of CAC/HP basic models.[93] In this NOPR, DOE is proposing to retain the current CLH and HLH estimates in appendix M1, for use in conjunction

[91] *See www.caiso.com/Documents/EnergyStorage-PerspectivesFromCalifornia-Europe.pdf.*

[92] In its simplest form, thermal storage involves using excess energy to heat/cool, melt or vaporize a material so that this stored energy can be recovered later. Heat pumps with thermal energy storage can store energy during times when electricity prices are low and release it during peak demand hours.

[93] *See* Table 21 of appendix M1 for the current CLH and HLH estimates used for rating values.

with SEER2 and HSPF2 representations. However, DOE is also proposing new estimates for CLH and HLH for use in conjunction with the proposed appendix M2 efficiency metrics, SCORE and SHORE. Specifically, DOE is proposing to use 1,457 and 972 hours as estimates for CLH and HLH, respectively, for use in conjunction with SCORE and SHORE representations. Unlike SEER2 and HSPF2, SCORE and SHORE are integrated metrics (that include off-mode and standby power) and use updated weather data for the United States' average number of conditioning and shoulder-season hours per temperature bin. Given the different metrics, DOE has tentatively determined that the proposed appendix M2 requires new CLH and HLH values for use by the FTC. Step-by-step derivations of proposed appendix M2 CLH and HLH values are presented in a docketed white paper titled ''Derivation of Proposed Appendix M2 Cooling Load Hours and Heating Load Hours for the Federal Trade Commission.'' [94]

2. Off-Mode Power

Off-mode power, $P_{W,OFF,}$ is a required represented value for all CAC/HPs, as specified in 10 CFR 429.16(a)(1). Currently, section 3.13 of appendix M1 includes testing instructions to determine off mode power ratings for CAC/HPs. As discussed in section III.F.1, the revised appendix M1 incorporates by reference AHRI 210/240–202X Draft. Section 11.2.3 and appendix H of AHRI 210/240–202X Draft include the same test instructions to determine $P_{W,OFF}$ as are present in the current appendix M1 and therefore no changes are required when representation are made per appendix M1.

However, as discussed in section III.F.1 of this NOPR, the metrics applicable to appendix M2, SCORE and SHORE, incorporate off-mode power consumption, unlike the current cooling and heating metrics SEER2 and HSPF2, respectively. As such, requiring representation of $P_{W,OFF}$ would be redundant for appendix M2. Therefore, DOE is proposing to clarify at 10 CFR 429.16(a)(2) that represented values of $P_{W,OFF}$ are only required when testing in accordance with appendix M1.

Additionally, 10 CFR 429.16(b)(2)(ii) currently allows flexibility for manufacturers to not test each individual model/combination (or tested combination) for $P_{W,OFF,}$ but at a minimum, test at least one individual model/combination for $P_{W,OFF}$ among individual models/combinations with similar off-mode construction. DOE is retaining this flexibility for testing to appendix M1. DOE is also extending similar flexibility for determining off-mode power values P_1 (off-mode power in shoulder season) and P_2 (off-mode power in heating season), which are used in the calculation of the SCORE and SHORE metrics when testing to appendix M2, but for which DOE is not proposing to require represented values.

Specifically, DOE is proposing at 10 CFR 429.16(b)(2)(iii) that when testing in accordance with appendix M2 and determining SCORE and SHORE, each individual model/combination is not required to be tested for values of P_1 (off-mode power in shoulder season) and P_2 (off-mode power in heating season). Instead, at a minimum, among individual models/combinations with similar off-mode construction (even spanning different models of outdoor units), a manufacturer must test at least one individual model/combination, for which P_1 and P_2 are the most consumptive.

Issue 3: DOE requests comment on its proposal at 10 CFR 429.16(b)(2)(iii) to extend testing flexibility to P1 (off-mode power in shoulder season) and P2 (off-mode power in heating season) when determining SCORE and SHORE, such that each individual model/combination is not required to be tested for values of P1 and P2.

3. AEDM Tolerance for SCORE and SHORE

DOE's existing regulations allow the use of an AEDM, in lieu of testing, to simulate the efficiency of CAC/HPs. 10 CFR 429.16(d). For models certified with an AEDM, results from DOE verification tests are subject to certain tolerances when compared to certified ratings. 10 CFR 429.70(e)(5)(v). The current tolerance specified for efficiency metrics for CAC/HPs (*i.e.,* SEER2, HSPF2, and EER2) requires that the result from the DOE verification test must be greater than or equal to 0.95 multiplied by the certified represented value. To maintain consistency with the existing efficiency metrics, DOE is proposing to extend the same tolerance requirement to the new efficiency metrics measured per appendix M2—SCORE and SHORE.

4. Removal of the AEDM Exception for Split-System CAC/HPs

Currently, the AEDM requirements at 10 CFR 429.70€ allow that, until July 1, 2024, non-space-constrained single-split-system CAC/HPs rated based on testing in accordance with appendix M1 are allowed to test a single-unit sample from 20 percent of the basic models distributed in commerce to validate the AEDM. On or after July 1, 2024, validation of the AEDM has to be based on complete testing of each basic model. *See* 10 CFR 429.70(e)(2)(i)(A). Corresponding provisions are also included at 10 CFR 429.16, paragraphs (b)(2)(i) and (c)(1)(i)(B).

Since amendments proposed in this NOPR are not expected to be finalized and made effective before July 1, 2024, the aforementioned AEDM exception for non-space-constrained single-split-system CAC/HPs would no longer apply at the time this rulemaking finalizes. As such, DOE is proposing to remove the date-based application of the AEDM requirement and instead clarifies that AEDM validation for all CAC/HPs, including non-space-constrained single-split-system CAC/HPs, must be based on complete testing of each basic model.

J. Enforcement Provisions

1. Verifying Cut-Out and Cut-In Temperatures

As discussed in section III.E.3 of this NOPR, appendix J of AHRI 210/240–202X Draft and AHRI 1600–202X Draft—which DOE is proposing to incorporate by reference—includes a test to determine cut-out and cut-in temperatures (*i.e.,* T_{off} and T_{on} respectively) that is applicable to all HPs. To enable DOE to verify certified cut-out and cut-in temperatures using the test methods in appendix K of the AHRI drafts, DOE is proposing product-specific provisions at 10 CFR 429.134(k)—specifically, DOE is proposing that for assessment and enforcement testing of CHP models, the cut-out and cut-in temperatures may be verified using the method in appendix J and that if this method is conducted, the cut-in and cut-out temperatures determined using this method will be used to calculate the relevant heating metric for purposes of compliance.

DOE will consider certification requirements for CAC/HPs, including the potential requirement for certification of cut-out and cut-in temperatures, in a separate rulemaking.

2. Controls Verification Procedure

As discussed in section III.E.1.d of this NOPR, appendix I of AHRI 210/240–202X Draft and AHRI 1600–202X Draft—which DOE proposes to incorporate by reference—includes a CVP to verify compliance of system operation with the variable-capacity compressor system definition and consistency of fixed-position settings for the compressor and indoor fan used in

[94] This paper is available for reference in Docket No. EERE–2022–BT–TP–0028.

steady-state tests with native control operation.

DOE is proposing provisions at 10 CFR 429.134(k) to establish requirements for DOE's use of the CVP for the purposes of assessment and enforcement testing. DOE is proposing that after conducting the CVP, which itself would be performed after an assessment or enforcement test using the DOE test procedure (*i.e.,* a certification test using Appendix M1 or Appendix M2, as applicable), if a unit is determined to be either a variable-capacity compressor system, variable capacity certified, single-capacity system, or variable capacity certified, two-capacity system, and meets the tolerances on capacity measurement (+/−6 percent) and efficiency [95] (+/−10 percent) for the full and minimum load CVP intervals, the efficiency metrics for the unit will be evaluated by conducting the prescribed DOE rating tests per Appendix M1 or Appendix M2 applicable to that system. These tests will be conducted based on the override instructions from the manufacturer for setting the appropriate compressor and fan speeds for each test.

However, if either of the full or minimum load CVP intervals fail to meet the required tolerances, and the control device allows adjustment of the compressor and indoor blower speeds,[96] DOE will conduct certification tests by setting the speeds for the tests to the average values observed during the corresponding failed CVP interval.[97] If either of the full or minimum load CVP intervals fail to meet the required tolerances, and the control device does not allow adjustment of the compressor and indoor blower speeds, DOE will use average capacity and power(s) or, for CVP intervals that do not meet the operating tolerances and condition tolerances, time averaged integrated capacity and time averaged integrated power(s), measured during the CVP, in order to calculate SEER2, HSPF2 and EER2 for appendix M1, and SCORE, SHORE and EER2, for appendix M2. For certification tests that do not have a corresponding CVP interval, the corresponding efficiency will be calculated by adjusting the capacity and efficiency, by application of a ratio to the corresponding CVP interval.[98]

For CHPs determined to be variable capacity certified, single capacity system, or variable capacity certified, two capacity system that are certified/marketed for use with only a proprietary control device, DOE may utilize two options, (1) contact the manufacturer to provide override control instructions consistent with the full and, if applicable, minimum speed operation observed during the CVP, to enable tests without a corresponding CVP interval to be conducted at the appropriate speeds, or (2) conduct the tests for $H_{1,Nom}$, $H_{2,Full}$, $H_{2,Low}$ and $H_{3,Low}$, as applicable, using the certified instructions, and for other certification tests, the corresponding efficiency will be calculated by adjusting the capacity and efficiency, by application of a ratio to the corresponding CVP interval.[99] Otherwise, the same simulated thermostat low voltage signal that resulted in in full speed compressor operation for the full load intervals shall be used for all certification full load tests (for variable capacity certified, single capacity system, or variable capacity certified, two capacity systems), and the same simulated thermostat low voltage signal that resulted in low speed compressor operation for the low load intervals, shall be used for all certification low load tests (for variable capacity certified, two capacity system).

DOE will address any associated certification requirements for the CVP in a separate rulemaking.

Issue 4: DOE requests comment on its proposals related to enforcement provisions when conducting the CVP.

K. Test Procedure Costs and Impact

EPCA requires that test procedures proposed by DOE not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3)) As discussed, DOE proposes to update the current Federal test procedure for CAC/HPs at appendix M1 consistent with the most recent draft version of the relevant industry consensus test procedure, AHRI 210/240–202X Draft. DOE is also proposing a new Federal test procedure at 10 CFR 430, subpart B, appendix M2, consistent with the draft version of the industry consensus test procedure, AHRI 1600–202X Draft. Appendix M2 would not be required for use until the compliance date of amended standards for CAC/HPs. DOE also proposes to amend its representation and enforcement provisions for CAC/HPs.

1. Appendix M1

In this NOPR, DOE proposes to update its regulations at 10 CFR part 430, subpart B, appendix M1 by incorporating by reference AHRI 210/240–202X Draft and relevant industry standards referenced in AHRI 210/240–202X Draft (ANSI/ASHRAE 37–2009, ANSI/ASHRAE 16–2016, and ANSI/ASHRAE 116–2010), and amending certain provisions for representations and enforcement in 10 CFR part 429, consistent with the changes proposed to the test procedure. The proposed revisions to appendix M1 would retain the current efficiency metrics (*i.e.,* EER2, SEER2, and HSPF2). The proposed testing requirements in appendix M1 are those in AHRI 210/240–202X Draft, which in turn references ANSI/ASHRAE 37–2009, ANSI/ASHRAE 16–2016, and ANSI/ASHRAE 116–2010.

DOE has tentatively determined that the proposed amendments to appendix M1 and the proposed representation and enforcement provisions would improve the representativeness, accuracy, and reproducibility of the test results and would not be unduly burdensome for manufacturers to conduct. DOE has also tentatively determined that the proposed amendments would not result in an increase in testing cost from the current test procedure. The proposed revisions to the test procedure in appendix M1 for measuring EER2, SEER2, and HSPF2 per AHRI 210/240–202X Draft would not increase third-party laboratory testing costs per unit relative to the current DOE test procedure. DOE estimates the current costs for physical testing, including off-mode testing, to range from $10,800 to $19,800, depending on the configuration of the CAC/HP (single-stage, two-stage, variable-capacity). Further, DOE has tentatively concluded that the proposed revisions to the test procedure in appendix M1 would not change efficiency ratings for CAC/HPs, and therefore would not require retesting or redesign solely as a result of DOE's adoption of the proposed amendments to the DOE test procedure, if made final.[100]

[95] EER2 for cooling load intervals, and COP2 for heating load intervals

[96] For the purpose of the CVP, ''adjustment'' means that the control device has the ability to make discrete adjustments, as required, to the compressor and indoor blower speeds without the need of any additional hardware or non-publicly available software.

[97] For tests that do not correspond to any load intervals of the CVP, DOE will adjust the compressor speed as follows: the compressor speeds for tests B_{full}, B_{low}, $H_{1,full}$, $H_{2,full}$, $H_{2,low}$ and $H_{0,low}$, will be set at the same speeds observed in the CVP load intervals associated with the A_{full}, F_{low}, $H_{3,full}$, $H_{3,full}$, and $H_{1,low}$ tests, respectively.

[98] As an example, the capacity at B_{full} condition, $Q_{B,Full,}$ will be calculated by the following equation: $Q_{B,Full,} = Q_{B,Full,Certification} \times Q_{CVP,A,Full}/Q_{A,Full,Certification}$, where $Q_{B,Full,Certification}$ is the capacity at B_{full} condition, $Q_{CVP,A,Full}$ is the full load interval capacity in cooling mode, and $Q_{A,Full,Certification}$ is the capacity at A_{full} condition.

[99] As an example, the capacity at HO_{Low} condition, $Q_{H0,Low}$, will be calculated by the following equation: $Q_{HO,Low,} = Q_{H0,Low,Certification} \times Q_{CVP,H1,Low}/Q_{H,Low,,Certification}$.

[100] Manufacturers are not required to perform laboratory testing on all basic models. In

As discussed in section III.E.1.(d) of this NOPR, DOE proposes to include a CVP in its enforcement regulations to validate whether override of modulating components in regulatory tests for variable-capacity compressor systems is consistent with native control operation. The proposed CVP for variable-capacity compressor systems in appendix I of AHRI 210/240–202X is not mandatory for manufacturers to perform, therefore, the proposed inclusion of this provision in DOE's enforcement regulations clarifies the approach DOE would follow for potential enforcement testing. To the extent that a manufacturer has not already verified the appropriateness of the fixed performance during regulatory tests as compared to native control operation (*i.e.,* the system may currently be improperly certified), a manufacturer may need to adjust fixed-speed overrides used in regulatory tests in accordance with the proposed CVP and subsequently re-run the regulatory tests. However, having no strong evidence to the contrary, DOE expects that current variable-capacity certifications are generally consistent with system performance. Thus, DOE concludes that any such cost to verify performance and potentially retest is negligible.

As explained in section III.E.2 of this NOPR, a new definition for CCHPs is introduced in AHRI 210/240–202X Draft, for which the $H4_{full}$ test (outdoor dry-bulb temperature of 5 °F) will be mandatory, which is otherwise optional for CHPs. However, this test and claim of CCHP status is optional. Also, DOE anticipates that units that will certify as CCHPs are most likely to be already testing at the 5 °F condition, and hence no added costs or test burden are expected to be associated with them.

The proposal for determination of cut-in and cut-out temperatures in DOE's enforcement provisions, as laid out in appendix J of the AHRI 210/240–202X Draft, would not be required for manufacturer testing. Thus, it will not cause manufacturers to incur any additional costs or burden.

As explained in section III.F.5 of this NOPR, AHRI 210/240–202X Draft introduced a definition for mandatory circulation systems. DOE is currently unaware of any CAC/HPs equipped with these systems, and they are anticipated to become more commonplace once A2L refrigerant regulations are enforced. CAC/HPs equipped with mandatory circulation systems will need to have their cyclic degradation coefficients evaluated using the respective cyclic tests, which are otherwise optional. Since cyclic tests are already often conducted by manufacturers to improve upon the default cyclic degradation coefficients, and because it is unclear whether any systems having such mandatory circulation will be introduced, DOE considers that there will be no significant increase in cost or test burden associated with the requirement for CAC/HPs equipped with mandatory circulation systems to conduct cyclic tests.

Issue 5: DOE requests comment on its tentative determination that the proposed amended appendix M1 would not require re-testing or result in any increase in test cost as compared to the existing appendix M1.

2. Appendix M2

As explained previously, DOE proposes to establish new regulations at 10 CFR 430, subpart B, appendix M2 as follows: (1) incorporate by reference AHRI 1600–202X Draft, and relevant industry standards referenced in AHRI 1600–202X Draft (ANSI/ASHRAE 37–2009, ANSI/ASHRAE 16–2016, and ANSI/ASHRAE 116–2010); and (2) establish provisions for determining SCORE and SHORE for CAC/HPs. Appendix M2 would not be required for testing until the compliance date of any future new standards for CAC/HPs based on the SCORE and SHORE metrics proposed in appendix M2. The proposed testing requirements in appendix M2 are those in AHRI 1600–202X Draft, which in turn references ANSI/ASHRAE 37–2009, ANSI/ASHRAE 16–2016, and ANSI/ASHRAE 116–2010.

DOE has tentatively determined that the proposed amendments in appendix M2 would be representative of average use cycle, not be unduly burdensome for manufacturers to conduct, and not result in increased testing cost as compared to the current test procedure. The proposed revisions to the test procedure in appendix M2 for measuring EER2, SCORE, and SHORE per AHRI 1600–202X Draft would not increase third-party laboratory testing costs per unit relative to the current DOE test procedure. DOE estimates the costs of physical testing, for the new metrics SCORE and SHORE to range from $10,800 to $19,800, same as that for appendix M1, depending on the configuration of the CAC/HP (*e.g.,* single-stage, two-stage, variable-capacity). DOE has tentatively concluded that the proposed revisions to the test procedure in appendix M2 would change efficiency ratings for CAC/HPs—however, testing and recertification based on appendix M2 would not be required until DOE adopts any amended CAC/HP standards in terms of the new metrics in a future energy conservation standards rulemaking.

As previously mentioned in this NOPR, the AHRI 1600–202X Draft introduces new cooling and heating performance metrics, SCORE and SHORE, as replacements for the current cooling, heating, and off-mode performance metrics, SEER2, HSPF2, and $P_{W,OFF}$, used to determine the measured efficiency of CAC/HPs. Unlike SEER2 and HSPF2, these new metrics account for the off-mode power consumption of auxiliary components, including crankcase heaters and indoor fans utilizing constant circulation for both SCORE and SHORE, as well as base pan heaters for SHORE.[101] The off-mode power consumption of auxiliary components is determined using appendix G of the AHRI 1600–202X Draft. This appendix includes measurement of power for base pan heaters and constant circulation fans, which are not included in the current test procedure measurements to determine off-mode power. The measurements are otherwise identical to those required by the current test, although the calculations used to determine off-mode power are different. Measurements of base pan heater power and constant circulation power may require separate power measurement instrumentation to be applied for the base pan heater, and may require a brief power measurement test period for constant circulation, both test method additions which represent minor test burden increase and would be applicable only for a minority of models. Hence, adoption of the new cooling and heating metric would not result in significant increase in testing costs as compared to the current test procedure.

The other proposed amendments mainly affect calculations and, other than potentially imposing limits on airflow settings (item (e) in this paragraph), will not affect testing. The proposed amendments are (a) revising

accordance with 10 CFR 429.16, CAC/HP manufacturers may elect to use AEDMs. An AEDM is a computer modeling or mathematical tool that predicts the performance of non-tested basic models. These computer modeling and mathematical tools, when properly developed, can provide a means to predict the energy usage or efficiency characteristics of a basic model of a given covered product or equipment and to reduce the burden and cost associated with testing.

[101] As described in section III.F.1.a of this NOPR, the off-mode power consumption definition in appendix M1 includes energy use for all operating modes not associated with times that the system is providing cooling or heating. Thus, off-mode in the context of the CAC/HP test procedure includes operating modes that would be interpreted as standby or active modes under IEC 62301.

the demand defrost credit for CHPs equipped with demand defrost systems; (b) accounting for the additional power use from supplementary heat during defrost by introducing defrost heat debit and the defrost overrun mode; (c) updating the building load lines and temperature bin hours for calculation of the new seasonal metrics SCORE and SHORE; (d) revising the default fan power coefficients for coil-only systems; and (e) imposing air flow limits to address inadequate dehumidification. Thus, DOE does not anticipate these additional amendments will cause any increased test procedure costs.

Issue 6: DOE requests comment on its tentative understanding of the impact of the test procedure proposals in this NOPR, particularly regarding DOE's initial estimates of the cost impacts associated with the proposed appendix M2. DOE also requests comment on the cost of testing CAC/HPs in accordance with AHRI 1600–202X Draft compared to DOE's estimated appendix M2 testing costs for physical testing ranging from $10,800 to $18,000, which are unchanged from the appendix M1 testing costs.

L. Compliance Date and Waivers

EPCA prescribes that, if DOE amends a test procedure, all representations of energy efficiency and energy use, including those made on marketing materials and product labels, must be made in accordance with that amended test procedure, beginning 180 days after publication of such a test procedure final rule in the **Federal Register**. (42 U.S.C. 6293(c)(2)) To the extent the modified test procedure proposed in this document is required only for the evaluation and issuance of updated efficiency standards, use of the modified test procedure, if finalized, would not be required until the compliance date of updated standards. Section 8(e) of appendix A 10 CFR part 430 subpart C.

If DOE were to publish an amended test procedure, EPCA provides an allowance for individual manufacturers to petition DOE for an extension of the 180-day period if the manufacturer may experience undue hardship in meeting the deadline. (42 U.S.C. 6293(c)(3)) To receive such an extension, petitions must be filed with DOE no later than 60 days before the end of the 180-day period and must detail how the manufacturer will experience undue hardship. (*Id.*)

Upon the compliance date of test procedure provisions of an amended test procedure, should DOE issue a such an amendment, any waivers that had been previously issued and are in effect that pertain to issues addressed by such provisions are terminated. 10 CFR 430.27(h)(3). Recipients of any such waivers would be required to test the products subject to the waiver according to the amended test procedure as of the compliance date of the amended test procedure. The amendments proposed in this document pertain to issues addressed by the interim waiver granted to Samsung HVAC America LLC (88 FR 36558, Case No. 2022–009). To the extent that such an interim waiver permit the petitioner to test according to an alternate test procedure to appendix M1, the interim waiver will terminate on the date the amendments to the appendix M1 test procedure take effect (*i.e.,* 180 days after publication of the test procedure final rule in the **Federal Register**).

Notably, the amendments proposed in this document do not pertain to issues addressed by the interim waiver granted to Johnson Controls Inc. (''JCI'') (88 FR 72449, Case No. 2023–005). This interim waiver permits JCI to test certain basic models of CAC/HPs that use variable speed, oil-injected scroll compressors (''VSS systems'') with a 72-hour break-in period, in lieu of the 20-hour break-in limit prescribed in appendix M1. (*Id.*) Because the 72-hour break-in period permitted to VSS systems listed in JCI's petition is unique to the CAC/HP market, DOE surmises that amendments to address this issue do not belong in either of the proposed Federal test procedures for CAC/HPs (*i.e.,* appendix M1 or appendix M2). However, DOE notes that JCI may continue to request a waiver to extend the allowable break-in period for its VSS systems. To the extent the interim waiver permits JCI to test according to an alternate test procedure to appendix M1, the interim waiver will terminate on the date testing is required according to appendix M2, which will occur on the compliance date for updated efficiency standards. DOE notes that JCI may petition for another waiver at the time testing is required according to appendix M2.

IV. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866, 13563, and 14094

Executive Order (''E.O.'') 12866, ''Regulatory Planning and Review,'' as supplemented and reaffirmed by E.O. 13563, ''Improving Regulation and Regulatory Review,'' 76 FR 3821 (Jan. 21, 2011) and E.O. 14094, ''Modernizing Regulatory Review,'' 88 FR 21879 (April 11, 2023), requires agencies, to the extent permitted by law, to (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public. DOE emphasizes as well that E.O. 13563 requires agencies to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. In its guidance, the Office of Information and Regulatory Affairs (''OIRA'') in the Office of Management and Budget (''OMB'') has emphasized that such techniques may include identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. For the reasons stated in the preamble, this proposed regulatory action is consistent with these principles.

Section 6(a) of E.O. 12866 also requires agencies to submit ''significant regulatory actions'' to OIRA for review. OIRA has determined that this proposed regulatory action does not constitute a ''significant regulatory action'' under section 3(f) of E.O. 12866. Accordingly, this action was not submitted to OIRA for review under E.O. 12866.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (''IRFA'') for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19,

2003, to ensure that the potential impacts of its rules on small entities are properly considered during the DOE rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's website: *www.energy.gov/gc/office-general-counsel.* DOE reviewed this proposed rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. The following sections detail DOE's IRFA for this test procedure proposed rulemaking.

1. Description of Reasons Why Action Is Being Considered

DOE proposes to update the current Federal test procedure for CAC/HPs at appendix M1 consistent with the most recent draft version of the relevant industry consensus test procedure, AHRI 210/240–202X Draft. DOE is also proposing a new Federal test procedure at 10 CFR part 430, subpart B, appendix M2, consistent with the draft version of the industry consensus test procedure, AHRI 1600–202X Draft. Appendix M2 would not be effective until new standards are established for CAC/HPs that rely on metrics present in appendix M2. In this NOPR, DOE is proposing amendments to the test procedure for CAC/HPs in satisfaction of the 7-year review statutory requirement specified in EPCA. (42 U.S.C. 6292(a)(3) and 6293(b)(1)(A))

2. Objectives of, and Legal Basis for, Rule

Under 42 U.S.C. 6293, EPCA sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered products. EPCA requires that any test procedures prescribed or amended under this section be reasonably designed to produce test results which measure energy efficiency, energy use, or estimated annual operating cost of a covered product during a representative average use cycle or period of use and not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3))

EPCA also requires that, at least once every 7 years, DOE review test procedures for all type of covered products, including CAC/HPs, to determine whether amended test procedures would more accurately or fully comply with the requirements that the test procedures are: (1) reasonably designed to produce test results which reflect energy efficiency, energy use, and estimated operating costs during a representative average use cycle or period of use; and (2) not unduly burdensome to conduct. (42 U.S.C. 6293(b)(1)(A))

DOE is publishing this NOPR proposing amendments to the test procedure for CAC/HPs in satisfaction of the aforementioned obligations under EPCA.

3. Description and Estimated Number of Small Entities Regulated

For manufacturers of CAC/HPs, the Small Business Administration (''SBA'') has set a size threshold, which defines those entities classified as ''small businesses'' for the purposes of the statute. DOE used the SBA's small business size standards to determine whether any small entities would be subject to the requirements of the rule. (*See* 13 CFR part 121.) The equipment covered by this rule is classified under North American Industry Classification System (''NAICS'') code 333415,[102] ''Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing.'' The SBA sets a threshold of 1,250 employees or fewer for an entity to be considered as a small business for this category.

DOE used publicly available information to identify potential small businesses that manufacture CAC/HPs. DOE identified manufacturers using DOE's Compliance Certification Database (''CCD'') [103] and the prior CAC/HP rulemakings. DOE used the publicly available information and subscription-based market research tools (*e.g.,* reports from Dun & Bradstreet) [104] to identify 22 original equipment manufacturers (''OEMs'') of the covered equipment. Of the 22 OEMs, DOE identified five domestic manufacturers of CAC/HPs.

DOE expects manufacturers that certify to AHRI Directory of Certified Product Performance (''AHRI Directory'') [105] to have different potential regulatory costs from manufacturers that do not certify to the AHRI Directory. All five small OEMs certify their CAC/HPs to the AHRI Directory.

4. Description and Estimate of Compliance Requirements

This NOPR proposes to adopt updated industry test standards for CAC/HPs. DOE proposes to update the current Federal test procedure for CAC/HPs at appendix M1, consistent with the most recent draft version of the relevant industry consensus test procedure, AHRI 210/240–202X Draft. DOE is also proposing a new Federal test procedure at 10 CFR part 430, subpart B, appendix M2, consistent with the draft version of the industry consensus test procedure, AHRI 1600–202X Draft. More specific amendments to the DOE test procedure are summarized in the following subsections.

(a) Cost and Compliance Associated With Appendix M1

In appendix M1, DOE proposes to incorporate by reference AHRI 210/240–202X Draft for CAC/HPs and to amend certain provisions for representations and enforcement in 10 CFR part 429, consistent with the changes proposed to the test procedure. The proposed revisions to appendix M1 would retain the current efficiency metrics—EER2, SEER2, and HSPF2. The proposed testing requirements in appendix M1 are generally consistent with those in AHRI 210/240–202X Draft, which in turn references ANSI/ASHRAE 37–2009, ANSI/ASHRAE 16–2016, and ASHRAE 116–2010. This proposed revision to the test procedure in appendix M1 for measuring EER2, SEER2, and HSPF2 would not increase third-party laboratory testing costs per unit relative to the current DOE test procedure. The proposed CVP'' for variable-capacity compressor systems in appendix I of AHRI 210/240–202X is not mandatory for manufacturers to perform, and DOE considers these developmental costs to be negligible and not burdensome to manufacturers. The $H4_{full}$ test (outdoor dry-bulb temperature of 5 °F) will be mandatory, but DOE anticipates no added costs as units that will certify as CCHPs are likely currently testing at the 5 °F condition. The proposal for determination of cut-in and cut-out temperatures in appendix J of the AHRI 210/240–202X Draft would be included in DOE's enforcement provisions and would not be mandatory for manufacturer testing, and thus manufacturers will not incur additional costs. Additionally, CAC/HPs equipped with mandatory circulation systems will have their cyclic degradation coefficients evaluated using respective cyclic tests, but DOE anticipates no added costs to manufacturers since cyclic tests are already often conducted on CAC/HPs (regardless of whether they are equipped with a mandatory constant circulation system) to improve the default cyclic degradation coefficients.

DOE has tentatively concluded that the proposed revisions to the test procedure in appendix M1 would not change efficiency ratings for CAC/HPs,

[102] The size standards are listed by NAICS code and industry description and are available at *www.sba.gov/document/support-table-size-standards* (last accessed Sept. 22, 2023).

[103] DOE's Compliance Certification Database is available at *www.regulations.doe.gov/ccms* (last accessed Sept. 19, 2023).

[104] Dun & Bradstreet login available at *https://app.dnbhoovers.com.*

[105] The AHRI Directory of Certified Product Performance is available at *www.ahridirectory.org.*

and therefore would not require retesting or redesign solely as a result of DOE's adoption of this proposed amendment to the DOE test procedure, if made final.[106] Further, the proposed test procedure in appendix M1 would not increase third-part laboratory testing costs per unit; DOE estimates current costs for physical testing to range from $10,800 to $19,800, depending on the configuration of the CAC/HP (single-stage, two-stage, variable-capacity). Therefore, DOE does not expect that the test procedure amendments in appendix M1 would result in manufacturers, including small manufacturers, incurring additional testing costs.

(b) Cost and Compliance Associated With Appendix M2

In appendix M2, DOE proposes to establish a new test procedure that references the draft industry test procedure, AHRI 1600–202X Draft, for measuring new efficiency metrics, SCORE and SHORE. Appendix M2 would not be effective until new standards are established for CAC/HPs that rely on metrics present in appendix M2, should DOE adopt such standards. The proposed testing requirements in appendix M2 are generally consistent with those in AHRI 1600–202X Draft, which in turn references ANSI/ASHRAE 37–2009, ANSI/ASHRAE 16–2016, and ASHRAE 116–2010. This proposed revision to the test procedure in appendix M2 for measuring EER2, SCORE, and SHORE would not increase third-party laboratory testing costs per unit relative to the current DOE test procedure. The standby and off-mode power consumption of auxiliary components is determined using appendix G of the AHRI 1600–202X Draft and does not differ substantially from the process to determine off-mode power from the current version of appendix M1, in section 3.13. The adoption of the new cooling and heating metric would not result in increased testing costs as compared to the current test procedure. Other proposed amendments will not affect testing cost, which include (a) building load lines and temperature bin hours for calculation of SCORE and SHORE, (b) default fan power coefficients for coil-only systems, and (c) air flow limits to address inadequate dehumidification.

The testing cost will not increase with appendix M2. DOE estimates the costs of physical testing for the new metrics SCORE and SHORE to range from $10,800 to $18,000, depending on the configuration of the CAC/HP (single-stage, two-stage, variable-capacity). Additionally, DOE allows the use of AEDMs in lieu of physically testing all basic models. The use of an AEDM is less costly than physical testing of CAC/HP models; DOE estimates the cost to develop an AEDM to be $16,860 per AEDM for a basic model, which includes the cost of physical testing done at a third-party laboratory to validate the AEDM.[107] The development of the AEDM would reduce the need for physical testing on the part of manufacturers. Once the AEDM is developed, DOE estimates that it would take 5 minutes of an engineer's time [108] to determine efficiency for each individual model within a basic model using the AEDM.

DOE understands all manufacturers currently certifying in the AHRI Directory (including small businesses) will be testing their models in accordance with AHRI 1600–202X Draft, the industry test procedure DOE is proposing to reference at appendix M2. As stated, testing and certification of the SCORE and SHORE metrics will not be required until the compliance date of any future energy conservation standards based on these metrics; however, DOE anticipates manufacturers will need to re-test their models to rate them in terms of the SCORE and SHORE metrics to comply with the AHRI certification program, and the re-rating will occur prior to a future energy conservation standards rulemaking. As a result, DOE has tentatively determined that the proposed test procedure amendments would not add any additional testing burden to manufacturers. Therefore, the proposed test procedure amendments in appendix M2 would not add any additional testing burden to the five small domestic manufacturers who certify in the AHRI database.

Issue 7: DOE requests comment on the number of small business OEMs of CAC/HPs, their participation in the AHRI Directory, and associated compliance costs.

5. Duplication, Overlap, and Conflict With Other Rules and Regulations

DOE is not aware of any rules or regulations that duplicate, overlap, or conflict with the rule being considered.

6. Significant Alternatives to the Rule

DOE proposes to amend the CAC/HPs test procedure in reference to industry standards in both appendices M1 and M2. DOE proposes to incorporate by reference AHRI 210/240–202X Draft and the subsequent relevant standards it references (ANSI/ASHRAE 16–2016, ANSI/ASHRAE 37–2009, and ASHRAE 116–2010) as the basis for the updated appendix M1 test procedure. Similarly, DOE proposes to incorporate by reference AHRI 1600–202X Draft and the subsequent relevant standards it references (ANSI/ASHRAE 16–2016, ANSI/ASHRAE 37–2009, and ASHRAE 116–2010) as the basis for the new appendix M2 test procedure. DOE considered alternative test methods and modifications to the proposed test procedures in appendices M1 and M2 for CAC/HPs. However, alternatives deviating from the industry standard would burden manufacturers with additional costs for separate test procedures. DOE has tentatively determined that there are no better alternatives than the proposed test procedures, in terms of both meeting the agency's objectives and reducing burden on manufacturers. Adoption of alternatives that do not incorporate the consensus industry test procedures would increase testing costs on small manufacturers. Therefore, DOE is proposing to amend the existing DOE test procedure for CAC/HPs through incorporation by reference of AHRI 210/240–202X Draft and AHRI 1600–202X Draft with the additional modifications as discussed throughout this NOPR.

In addition, individual manufacturers may petition for a waiver of the applicable test procedure. 10 CFR 431.401. Also, section 504 of the Department of Energy Organization Act, 42 U.S.C. 7194, provides authority for the Secretary to adjust a rule issued under EPCA in order to prevent ''special hardship, inequity, or unfair distribution of burdens'' that may be imposed on that manufacturer as a result of such rule. Manufacturers should refer to 10 CFR part 1003 for additional details.

C. Review Under the Paperwork Reduction Act of 1995

Manufacturers of CAC/HPs must certify to DOE that their products comply with any applicable energy conservation standards. To certify

[106] Manufacturers are not required to perform laboratory testing on all basic models. In accordance with 10 CFR 429.16, CAC/HP manufacturers may elect to use AEDMs. An AEDM is a computer modeling or mathematical tool that predicts the performance of non-tested basic models. These computer modeling and mathematical tools, when properly developed, can provide a means to predict the energy usage or efficiency characteristics of a basic model of a given covered product or equipment and to reduce the burden and cost associated with testing.

[107] AEDM = physical testing cost + (time to develop AEDM * engineering technician wage) = $14,400 + (60 hours * $41/hour).

[108] DOE estimates a fully-burdened wage rate of $41 per hour for an engineering technician based on Bureau of Labor Statistics median wage data for mechanical engineering technicians and benefits data for the private sector.

compliance, manufacturers must first obtain test data for their products according to the DOE test procedures, including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including CAC/HPs. (*See generally* 10 CFR part 429.) The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (''PRA''). This requirement has been approved by OMB under OMB control number 1910–1400. Public reporting burden for the certification is estimated to average 35 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

DOE is not proposing to amend the certification or reporting requirements for CAC/HPs in this NOPR. DOE will address certification requirements for CAC/HPs in a separate rulemaking for certification, compliance, and enforcement. DOE will address changes to OMB Control Number 1910–1400 at that time, as necessary.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

D. Review Under the National Environmental Policy Act of 1969

In this NOPR, DOE proposes test procedure amendments that will be used to develop and implement future energy conservation standards for CAC/HPs. DOE has determined that this proposed rule falls into a class of actions that are categorically excluded from review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and DOE's implementing regulations at 10 CFR part 1021. Specifically, DOE has determined that adopting test procedures for measuring energy efficiency of consumer products and industrial equipment is consistent with activities identified in 10 CFR part 1021, subpart D, appendix A, sections A5, and A6. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

E. Review Under Executive Order 13132

Executive Order 13132, ''Federalism,'' 64 FR 43255 (August 4, 1999) imposes certain requirements for agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this proposed rule and has determined that it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this proposed rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297(d)) No further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

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

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (''UMRA'') requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed ''significant intergovernmental mandate'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820; also available at *www.energy.gov/gc/office-general-counsel.* DOE examined this proposed rule according to UMRA and its statement of policy and determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of $100 million or more in any year, so these requirements do not apply.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family

Policymaking Assessment for any rule that may affect family well-being. This proposed rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

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

J. Review Under Treasury and General Government Appropriations Act, 2001

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

K. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OMB, a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that (1) is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

The proposed regulatory action to amend the test procedure for measuring the energy efficiency of CAC/HPs is not a significant regulatory action under Executive Order 12866. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Therefore, it is not a significant energy action, and, accordingly, DOE has not prepared a Statement of Energy Effects.

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

Under section 301 of the Department of Energy Organization Act (Pub. L. 95–91; 42 U.S.C. 7101), DOE must comply with section 32 of the Federal Energy Administration Act of 1974, as amended by the Federal Energy Administration Authorization Act of 1977. (15 U.S.C. 788; ''FEAA'') Section 32 essentially provides in relevant part that, where a proposed rule authorizes or requires use of commercial standards, the notice of proposed rulemaking must inform the public of the use and background of such standards. In addition, section 32(c) requires DOE to consult with the Attorney General and the Chairman of the Federal Trade Commission (''FTC'') concerning the impact of the commercial or industry standards on competition.

The proposed modifications to the test procedure for CAC/HPs would specifically reference testing methods contained in certain sections of the following commercial standards: AHRI 210/240–202X Draft, ANSI/ASHRAE 37–2009, ANSI/ASHRAE 16–2016, and ASHRAE 116–2010. DOE has evaluated these standards and is unable to conclude whether they fully comply with the requirements of section 32(b) of the FEAA (*i.e.,* whether it was developed in a manner that fully provides for public participation, comment, and review). DOE will consult with both the Attorney General and the Chairman of the FTC concerning the impact of these test procedures on competition, prior to prescribing a final rule.

M. Description of Materials Incorporated by Reference

In this NOPR, DOE proposes to incorporate by reference the following test standards:

AHRI Standard 210/240–202X Draft. This test standard is an update to AHRI 210/240–2023 (2020), and is a draft industry test procedure for measuring the heating and cooling capacity and efficiency of unitary air-source air conditioners and heat pumps with capacities less than 65,000 Btu/hour. The revised appendix M1 will be consistent with provisions in AHRI 210/240–202X Draft.

AHRI 1600–202X Draft. This test standard is a major update to AHRI 210/240–2023 (2020), and is a draft industry test procedure for measuring the heating and cooling capacity and efficiency of unitary air-source air conditioners and heat pumps with capacities less than 65,000 Btu/hour, including new seasonal cooling and heating efficiency metrics, namely SCORE and SHORE. The new appendix M2 will be consistent with provisions in AHRI 1600–202X Draft.

Copies of AHRI 210/240–202X Draft and AHRI 1600–202X Draft can be obtained from AHRI, 2311 Wilson Blvd., Suite 400, Arlington, VA 22201, (703) 524–8800, or found online at: *www.ahrinet.org.* Copies of the AHRI 210/240–202X Draft and AHRI 1600–202X Draft are also available in the docket for this proposed rulemaking.

If finalized versions of AHRI 210/240 and AHRI 1600 are not published before the test procedure final rule, or if there are substantive changes between the drafts and published versions of the standards that are not supported by stakeholder comments in response to this NOPR, DOE may adopt the substance of the AHRI 210/240–202X Draft and AHRI 1600–202X Draft or provide additional opportunity for comment on the final version of that industry consensus standard.

ANSI/ASHRAE 37–2009. This test standard is an industry-accepted test procedure that provides a method of test for many categories of air conditioning and heating equipment.

ANSI/ASHRAE 16–2016. This test standard is an industry-accepted test procedure that provides a method of test for room air conditioners, packaged terminal air conditioners, and packaged terminal heat pumps.

ASHRAE 116–2010. This test standard is an industry-accepted test procedure that provides a method of test for electrically driven, residential air-cooled air conditioners and heat pumps with cooling capacity of 65,000 Btu/hr. and less.

Copies of ANSI/ASHRAE 37–2009, ANSI/ASHRAE 16–2016 and ASHRAE 116–2010 are available on ASHRAE's website at *www.ashrae.org.*

V. Public Participation

A. Participation in the Webinar

The time and date of the webinar are listed in the **DATES** section at the beginning of this document. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants will be published on DOE's website *www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=48&action=viewlive*. Participants are responsible for ensuring their systems are compatible with the webinar software.

B. Procedure for Submitting Prepared General Statements for Distribution

Any person who has plans to present a prepared general statement may request that copies of his or her statement be made available at the public meeting. Such persons may submit requests, along with an advance electronic copy of their statement in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format, to the appropriate address shown in the **ADDRESSES** section at the beginning of this document. The request and advance copy of statements must be received at least one week before the public meeting and are to be emailed. Please include a telephone number to enable DOE staff to make follow-up contact, if needed.

C. Conduct of the Public Meeting

DOE will designate a DOE official to preside at the public meeting and may also use a professional facilitator to aid discussion. The meeting will not be a judicial or evidentiary-type public hearing, but DOE will conduct it in accordance with section 336 of EPCA. (42 U.S.C. 6306) A court reporter will be present to record the proceedings and prepare a transcript. DOE reserves the right to schedule the order of presentations and to establish the procedures governing the conduct of the public meeting. There shall not be discussion of proprietary information, costs or prices, market share, or other commercial matters regulated by U.S. anti-trust laws. After the public meeting, interested parties may submit further comments on the proceedings, as well as on any aspect of the rulemaking, until the end of the comment period.

The public meeting will be conducted in an informal conference style. DOE will present a general overview of the topics addressed in this proposed rulemaking, allow time for prepared general statements by participants, and encourage all interested parties to share their views on issues affecting this proposed rulemaking. Each participant will be allowed to make a general statement (within time limits determined by DOE), before the discussion of specific topics. DOE will allow, as time permits, other participants to comment briefly on any general statements.

At the end of all prepared statements on a topic, DOE will permit participants to clarify their statements briefly. Participants should be prepared to answer questions by DOE and by other participants concerning these issues. DOE representatives may also ask questions of participants concerning other matters relevant to this proposed rulemaking. The official conducting the public meeting will accept additional comments or questions from those attending, as time permits. The presiding official will announce any further procedural rules or modification of the previous procedures that may be needed for the proper conduct of the public meeting.

A transcript of the public meeting will be included in the docket, which can be viewed as described in the *Docket* section at the beginning of this document and will be accessible on the DOE website. In addition, any person may buy a copy of the transcript from the transcribing reporter.

D. Submission of Comments

DOE will accept comments, data, and information regarding this proposed rule before or after the public meeting, but no later than the date provided in the **DATES** section at the beginning of this proposed rule.[109] Interested parties may submit comments, data, and other information using any of the methods described in the **ADDRESSES** section at the beginning of this document.

[109] DOE has historically provided a 75-day comment period for test procedure NOPRs pursuant to the North American Free Trade Agreement, U.S.-Canada-Mexico (''NAFTA''), Dec. 17, 1992, 32 I.L.M. 289 (1993); the North American Free Trade Agreement Implementation Act, Public Law 103–182, 107 Stat. 2057 (1993) (codified as amended at 10 U.S.C.A. 2576) (1993) (''NAFTA Implementation Act''); and Executive Order 12889, ''Implementation of the North American Free Trade Agreement,'' 58 FR 69681 (Dec. 30, 1993). However, on July 1, 2020, the Agreement between the United States of America, the United Mexican States, and the United Canadian States (''USMCA''), Nov. 30, 2018, 134 Stat. 11 (*i.e.,* the successor to NAFTA), went into effect, and Congress's action in replacing NAFTA through the USMCA Implementation Act, 19 U.S.C. 4501 *et seq.* (2020), implies the repeal of E.O. 12889 and its 75-day comment period requirement for technical regulations. Thus, the controlling laws are EPCA and the USMCA Implementation Act. Consistent with EPCA's public comment period requirements for consumer products, the USMCA only requires a minimum comment period of 60 days. Consequently, DOE now provides a 60-day public comment period for test procedure NOPRs.

Submitting comments via www.regulations.gov. The *www.regulations.gov* web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment itself or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Otherwise, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (''CBI'')). Comments submitted through *www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery/courier, or postal mail. Comments and documents submitted via email, hand delivery/courier, or postal mail also will be posted to *www.regulations.gov.* If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your

contact information in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via postal mail or hand delivery/courier, please provide all items on a CD, if feasible, in which case it is not necessary to submit printed copies. No telefacsimiles (''faxes'') will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English, and that are free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email two well-marked copies: one copy of the document marked ''confidential'' including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

E. Issues on Which DOE Seeks Comment

Although DOE welcomes comments on any aspect of this proposal, DOE is particularly interested in receiving comments and views of interested parties concerning the following issues:

Issue 1: DOE requests feedback on its proposal to revise appendix M1 by making it consistent with the latest version of AHRI 210/240–202X Draft, for measuring the existing metrics, SEER2 and HSPF2.

Issue 2: DOE requests feedback on its proposal to establish a new appendix M2, to be consistent with the latest version of AHRI 1600–202X Draft, and to adopt the SCORE and SHORE metrics as determined under AHRI 1600–202X Draft in appendix M2 of the Federal test procedure for CAC/HPs.

Issue 3: DOE requests comment on its proposal to extend testing flexibility to P_1 (off-mode power in shoulder season) and P_2 (off-mode power in heating season) when determining SCORE and SHORE.

Issue 4: DOE requests comment on its proposals related to enforcement provisions when conducting the CVP.

Issue 5: DOE requests comment on its tentative understanding of the impact of the test procedure proposals in this NOPR, particularly regarding DOE's initial estimates of the cost impacts associated with the revised appendix M1.

Issue 6: DOE requests comment on its tentative understanding of the impact of the test procedure proposals in this NOPR, particularly regarding DOE's initial estimates of the cost impacts associated with the proposed appendix M2. DOE also requests comment on the cost of testing CAC/HPs in accordance with AHRI 1600–202X Draft compared to DOE's estimated appendix M2 testing costs for physical testing ranging from $10,800 to $18,000, which are unchanged from the appendix M1 testing costs.

Issue 7: DOE requests comment on the number of small business OEMs of CAC/HPs and their participation in the AHRI Directory.

Additionally, DOE welcomes comments on other issues relevant to the conduct of this rulemaking that may not specifically be identified in this document.

VI. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notice of proposed rulemaking and request for comment.

List of Subjects

10 CFR Part 429

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Small businesses.

10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Incorporation by reference, Intergovernmental relations, Small businesses.

Signing Authority

This document of the Department of Energy was signed on February 27, 2024, by Jeffrey Marootian, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE **Federal Register** Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on March 1, 2024.

Treena V. Garrett,

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

For the reasons stated in the preamble, DOE is proposing to amend parts 429 and 430 of Chapter II of Title 10, Code of Federal Regulations as set forth below:

PART 429—CERTIFICATION, COMPLIANCE, AND ENFORCEMENT FOR CONSUMER PRODUCTS AND COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 1. The authority citation for part 429 continues to read as follows:

Authority: 42 U.S.C. 6291–6317; 28 U.S.C. 2461 note.

■ 2. Amend § 429.4 by:

■ a. Redesignating paragraphs (c)(2) through (c)(7) as paragraphs (c)(3) through (c)(8); and

■ b. Adding new paragraphs (c)(2) and (c)(9).

The additions read as follows:

§ 429.4 Materials incorporated by reference.

* * * * *

(c) * * *

(2) AHRI Standard 210/240–202X, *202X Standard for Performance Rating of Unitary Air-Conditioning & Air-Source Heat Pump Equipment,* [version

and date TBD]; IBR approved for § 429.134.

* * * * *

(9) AHRI 1600–202X, *202X Standard for Performance Rating of Unitary Air-Conditioning & Air-Source Heat Pump Equipment,* [version and date TBD]; IBR approved for § 429.134.

* * * * *

■ 3. Amend § 429.16 by revising paragraphs (a)(1), (2), and (3)(i), (b)(2), and (3)(ii), (c)(1)(i)(B), (c)(1)(ii), (c)(3), (d)(2), and (f) to read as follows:

§ 429.16 Central air conditioners and central air conditioning heat pumps.

(a) * * *

(1) *Required represented values.* Determine the represented values (including as applicable, SEER2, EER2, HSPF2, $P_{W,OFF}$, SCORE, SHORE, cooling capacity, and heating capacity) for the individual models/combinations (or ''tested combinations'') specified in the following table.

TABLE 1 TO PARAGRAPH (a)(1)

Category	Equipment subcategory	Required represented values
Single-Package Unit	Single-Package Air Conditioner (AC) (including space-constrained).	Every individual model distributed in commerce.
	Single-Package Heat Pump (HP) (including space-constrained).	Every individual model distributed in commerce.
Outdoor Unit and Indoor Unit (Distributed in Commerce by Outdoor Unit Manufacturer (OUM)).	Single-Split-System AC with Single-Stage or Two-Stage Compressor (including Space-Constrained and Small-Duct, High Velocity Systems (SDHV)).	Every individual combination distributed in commerce. Each model of outdoor unit must include a represented value for at least one coil-only individual combination that is distributed in commerce and which is representative of the least efficient combination distributed in commerce with that particular model of outdoor unit. For that particular model of outdoor unit, additional represented values for coil-only and blower-coil individual combinations are allowed, if distributed in commerce.
	Single-Split System AC with Other Than Single-Stage or Two-Stage Compressor (including Space-Constrained and SDHV).	Every individual combination distributed in commerce, including all coil-only and blower-coil combinations.
	Single-Split-System HP (including Space-Constrained and SDHV).	Every individual combination distributed in commerce.
	Multi-Split, Multi-Circuit, or Multi-Head Mini-Split Split System—non-SDHV (including Space-Constrained).	For each model of outdoor unit, at a minimum, a non-ducted ''tested combination.'' For any model of outdoor unit also sold with models of ducted indoor units, a ducted ''tested combination.'' The ducted ''tested combination'' must comprise the highest static variety of ducted indoor unit distributed in commerce (*i.e.,* conventional, mid-static, or low-static). Additional representations are allowed, as described in paragraphs (c)(3)(i) and (ii) of this section, respectively.
	Multi-Split, Multi-Circuit, or Multi-Head Mini-Split Split System—SDHV.	For each model of outdoor unit, an SDHV ''tested combination.'' Additional representations are allowed, as described in paragraph (c)(3)(iii) of this section.
Indoor Unit Only Distributed in Commerce by Independent Coil Manufacturer (ICM).	Single-Split-System Air Conditioner (including Space-Constrained and SDHV).	Every individual combination distributed in commerce.
	Single-Split-System Heat Pump (including Space-Constrained and SDHV).	
	Multi-Split, Multi-Circuit, or Multi-Head Mini-Split Split System—SDHV.	For a model of indoor unit within each basic model, an SDHV ''tested combination.'' Additional representations are allowed, as described in paragraph (c)(3)(iii) of this section.
Outdoor Unit with no Match		Every model of outdoor unit distributed in commerce (tested with a model of coil-only indoor unit as specified in paragraph (b)(2)(i) of this section.

(2) $P_{W,OFF}$. Represented values of $P_{W,OFF}$ are only required when determining represented values in accordance with 10 CFR part 430, subpart B, appendix M1. If individual models of single-package systems or individual combinations (or ''tested combinations'') of split systems that are otherwise identical are offered with multiple options for off mode-related components, determine the represented value for the individual model/combination with the crankcase heater and controls that are the most consumptive. A manufacturer may also determine represented values for individual models/combinations with less consumptive off mode options; however, all such options must be identified with different model numbers for single-package systems or for outdoor units (in the case of split systems).

(3) *Refrigerants.* (i) If a model of outdoor unit (used in a single-split, multi-split, multi-circuit, multi-head mini-split, and/or outdoor unit with no match system) is distributed in commerce and approved for use with multiple refrigerants, a manufacturer must determine all represented values for that model using each refrigerant that can be used in an individual combination of the basic model (including outdoor units with no match

or ''tested combinations''). This requirement may apply across the listed categories in the table in paragraph (a)(1) of this section. A refrigerant is considered approved for use if it is listed on the nameplate of the outdoor unit.

* * * * *

(b) * * *

(2) * * *

(i) The table identifies the minimum testing requirements for each basic model that includes multiple individual models/combinations; if a basic model spans multiple categories or subcategories listed in the table, multiple testing requirements apply. For each basic model that includes only one individual model/combination, test that individual model/combination.

TABLE 2 TO PARAGRAPH (b)(2)(i)

Category	Equipment subcategory	Must test:	With:
Single-Package Unit	Single-Package AC (including Space-Constrained). Single-Package HP (including Space-Constrained).	The individual model with the lowest seasonal energy efficiency ratio 2 (SEER2) (when testing in accordance with appendix M1 to subpart B of part 430) or SCORE (when testing in accordance with appendix M2 to subpart B of part 430).	N/A.
Outdoor Unit and Indoor Unit (Distributed in Commerce by OUM).	Single-Split-System AC with Single-Stage or Two-Stage Compressor (including Space-Constrained and Small- Duct, High Velocity Systems (SDHV)).	The model of outdoor unit	A model of coil-only indoor unit.
	Single-Split-System HP with Single-Stage or Two-Stage Compressor (including Space-Constrained and SDHV).	The model of outdoor unit	A model of indoor unit.
	Single-Split System AC or HP with Other Than Single-Stage or Two-Stage Compressor having a coil-only individual combination (including Space-Constrained and SDHV).	The model of outdoor unit	A model of coil-only indoor unit.
	Single-Split System AC or HP with Other Than Single-Stage or Two-Stage Compressor without a coil-only individual combination (including Space-Constrained and SDHV).	The model of outdoor unit	A model of indoor unit.
	Multi-Split, Multi-Circuit, or Multi-Head Mini-Split Split System—non-SDHV (including Space-Constrained).	The model of outdoor unit	At a minimum, a ''tested combination'' composed entirely of non-ducted indoor units. For any models of outdoor units also sold with models of ducted indoor units, test a second ''tested combination'' composed entirely of ducted indoor units (in addition to the non-ducted combination). The ducted ''tested combination'' must comprise the highest static variety of ducted indoor unit distributed in commerce (*i.e.,* conventional, mid-static, or low-static).
	Multi-Split, Multi-Circuit, or Multi-Head Mini-Split Split System—SDHV.	The model of outdoor unit	A ''tested combination'' composed entirely of SDHV indoor units.
Indoor Unit Only (Distributed in Commerce by ICM).	Single-Split-System Air Conditioner (including Space-Constrained and SDHV).	A model of indoor unit	The least efficient model of outdoor unit with which it will be paired where the least efficient model of outdoor unit is the model of outdoor unit in the lowest SEER2 combination (when testing under appendix M1 to subpart B of part 430) or SCORE combination (when testing under appendix M2 to subpart B of part 430) as certified by the OUM. If there are multiple models of outdoor unit with the same lowest SEER2 (when testing under appendix M1 to subpart B of part 430) or SCORE (when testing under appendix M2 to subpart B of part 430) represented value, the ICM may select one for testing purposes.

TABLE 2 TO PARAGRAPH (b)(2)(i)—Continued

Category	Equipment subcategory	Must test:	With:
	Single-Split-System Heat Pump (including Space-Constrained and SDHV).	Nothing, as long as an equivalent air conditioner basic model has been tested. If an equivalent air conditioner basic model has not been tested, must test a model of indoor unit.	
	Multi-Split, Multi-Circuit, or Multi-Head Mini-Split Split System—SDHV.	A model of indoor unit	A "tested combination" composed entirely of SDHV indoor units, where the outdoor unit is the least efficient model of outdoor unit with which the SDHV indoor unit will be paired. The least efficient model of outdoor unit is the model of outdoor unit in the lowest SEER2 combination (when testing under appendix M1 to subpart B of part 430) or SCORE combination (when testing under appendix M2 to subpart B of part 430) as certified by the OUM. If there are multiple models of outdoor unit with the same lowest SEER2 represented value (when testing under appendix M1 to subpart B of part 430) or SCORE represented value (when testing under appendix M2 to subpart B of part 430), the ICM may select one for testing purposes.
Outdoor Unit with No Match.		The model of outdoor unit	A model of coil-only indoor unit meeting the requirements of section 4 of appendix M1 (when testing under appendix M1 to subpart B of part 430); or meeting the requirements of section 3 of appendix M2 (when testing under appendix M2 to subpart B of part 430).

(ii) When testing in accordance with appendix M1 to subpart B of part 430, each individual model/combination (or ''tested combination'') identified in paragraph (b)(2)(i) of this section is not required to be tested for $P_{W,OFF}$. Instead, at a minimum, among individual models/combinations with similar off-mode construction (even spanning different models of outdoor units), a manufacturer must test at least one individual model/combination for $P_{W,OFF}$.

(iii) When testing in accordance with appendix M2 to subpart B of part 430 and determining SCORE and SHORE, each individual model/combination (or ''tested combination'') identified in paragraph (b)(2)(i) of this section is not required to be tested for values of P_1 (off-mode power in shoulder season) and P_2 (off-mode power in heating Season). Instead, at a minimum, among individual models/combinations with similar off-mode construction (even spanning different models of outdoor units), a manufacturer must test at least one individual model/combination, for which P_1 and P_2 are the most consumptive.

(3) * * *

(ii) *SEER2, EER2, HSPF2, SCORE and SHORE.* Any represented value of the energy efficiency or other measure of energy consumption for which consumers would favor higher values shall be less than or equal to the lower of:

(A) The mean of the sample, where:

$$\bar{x} = \frac{1}{n}\sum_{i=1}^{n} x_i$$

and, $\bar{x}$ is the sample mean; n is the number of samples; and x_i is the ith sample; or,

(B) The lower 90 percent confidence limit (LCL) of the true mean divided by 0.95, where:

$$LCL = \bar{x} - t_{.90}\left(\frac{s}{\sqrt{n}}\right)$$

And $\bar{x}$ is the sample mean; s is the sample standard deviation; n is the number of samples; and $t_{0.90}$ is the t statistic for a 90 percent one-tailed confidence interval with n − 1 degrees of freedom (from appendix D). Round represented values of EER2, SEER2, HSPF2, SCORE and SHORE to the nearest 0.05.

* * * * *

(c) * * *

(1) * * *

(i) * * *

(B) The represented values of the measures of energy efficiency or energy consumption through the application of an AEDM in accordance with paragraph (d) of this section and § 429.70. An AEDM may only be used to determine represented values for individual models or combinations in a basic model (or separate approved refrigerants within an individual combination) other than the individual model or combination(s) required for mandatory testing under paragraph (b)(2) of this section.

(ii) When testing in accordance with appendix M1 to subpart B of part 430, for every individual model/combination within a basic model tested pursuant to paragraph (b)(2) of this section, but for which $P_{w,off}$ testing was not conducted, the represented value of $P_{w,off}$ may be assigned through, either:

(A) The testing result from an individual model/combination of similar off-mode construction; or

(B) The application of an AEDM in accordance with paragraph (d) of this section and § 429.70.

* * * * *

(3) *For multi-split systems, multi-circuit systems, and multi-head mini-split systems.* The following applies:

(i) When testing in accordance with appendix M1 to subpart B of part 430, or appendix M2 to subpart B of part 430, for basic models that include additional varieties of ducted indoor units (*i.e.,* conventional, low-static, or mid-static) other than the one for which representation is required in paragraph (a)(1) of this section, if a manufacturer chooses to make a representation, the manufacturer must conduct testing of a tested combination according to the requirements in paragraph (b)(3) of this section.

(ii) When testing in accordance with appendix M1 to subpart B of part 430, or appendix M2 to subpart B of part 430, for basic models that include mixed combinations of indoor units (any two kinds of non-ducted, low-static, mid-static, and conventional ducted indoor units), the represented value for the mixed combination is the mean of the represented values for the individual component combinations as determined in accordance with paragraph (b)(3) of this section.

(iii) When testing in accordance with appendix M1 to subpart B of part 430, or appendix M2 to subpart B of part 430, for basic models including mixed combinations of SDHV and another kind of indoor unit (any of non-ducted, low-static, mid-static, and conventional ducted), the represented value for the mixed SDHV/other combination is the mean of the represented values for the SDHV and other tested combination as determined in accordance with paragraph (b)(3) of this section.

(iv) All other individual combinations of models of indoor units for the same model of outdoor unit for which the manufacturer chooses to make representations must be rated as separate basic models, and the provisions of paragraphs (b)(1) through (3) and (c)(3)(i) through (iii) of this section apply.

(v) When testing in accordance with appendix M1 to subpart B of part 430, and with respect to $P_{w,off}$ only, for every individual combination (or ''tested combination'') within a basic model tested pursuant to paragraph (b)(2) of this section, but for which $P_{w,off}$ testing was not conducted, the representative values of $P_{w,off}$ may be assigned through either:

(A) The testing result from an individual model or combination of similar off-mode construction, or

(B) Application of an AEDM in accordance with paragraph (d) of this section and § 429.70.

(d) * * *

(2) *Energy efficiency.* Any represented value of the SEER2, EER2, HSPF2, SCORE, SHORE or other measure of energy efficiency of an individual model/combination for which consumers would favor higher values must be less than or equal to the output of the AEDM but no less than the standard.

* * * * *

(f) *Represented values for the Federal Trade Commission.* Use the following represented value determinations to meet the requirements of the Federal Trade Commission.

(1) *Annual Operating Cost—Cooling.* Determine the represented value of estimated annual operating cost for cooling-only units or the cooling portion of the estimated annual operating cost for air-source heat pumps that provide both heating and cooling, as follows:

(i) When using appendix M1 to subpart B of part 430, the product of:

(A) The quotient of the represented value of cooling capacity, in Btu's per hour as determined in paragraph (b)(3)(iii) of this section, and multiplied by 0.93 for variable speed heat pumps only, divided by the represented value of SEER2, in Btu's per watt-hour, as determined in paragraph (b)(3)(ii) of this section.

(B) The representative average use cycle for cooling of 1,000 hours per year;

(C) A conversion factor of 0.001 kilowatt per watt; and

(D) The representative average unit cost of electricity in dollars per kilowatt-hour as provided pursuant to section 323(b)(2) of the Act.

(ii) When using appendix M2 to subpart B of part 430, the product of:

(A) The quotient of the represented value of cooling capacity, in Btu's per hour as determined in paragraph (b)(3)(iii) of this section, and multiplied by 0.93 for variable speed heat pumps only, divided by the represented value of SCORE, in Btu's per watt-hour, as determined in paragraph (b)(3)(ii) of this section.

(B) The representative average use cycle for cooling of 1,457 hours per year;

(C) A conversion factor of 0.001 kilowatt per watt; and

(D) The representative average unit cost of electricity in dollars per kilowatt-hour as provided pursuant to section 323(b)(2) of the Act.

(2) *Annual Operating Cost—Heating.* Determine the represented value of estimated annual operating cost for air-source heat pumps that provide only heating or for the heating portion of the estimated annual operating cost for air-source heat pumps that provide both heating and cooling, as follows:

(i) When using appendix M1 to subpart B of part 430, the product of:

(A) The quotient of the represented value of cooling capacity (for air-source heat pumps that provide both cooling and heating) in Btu's per hour, as determined in paragraph (b)(3)(iii) of this section, or the represented value of heating capacity (for air-source heat pumps that provide only heating), as determined in paragraph (b)(3)(i)(D) of this section, divided by the represented value of HSPF2, in Btu's per watt-hour, calculated for Region IV, as determined in paragraph (b)(3)(ii) of this section;

(B) The representative average use cycle for heating of 1,572 hours per year;

(C) The adjustment factor of 1.15 (for heat pumps that are not variable speed) or 1.07 (for heat pumps that are variable speed), which serves to adjust the calculated design heating requirement and heating load hours to the actual load experienced by a heating system;

(D) A conversion factor of 0.001 kilowatt per watt; and

(E) The representative average unit cost of electricity in dollars per kilowatt-hour as provided pursuant to section 323(b)(2) of the Act;

(ii) When using appendix M2 to subpart B of part 430, the product of:

(A) The quotient of the represented value of cooling capacity (for air-source heat pumps that provide both cooling and heating) in Btu's per hour, as determined in paragraph (b)(3)(iii) of this section, or the represented value of heating capacity (for air-source heat pumps that provide only heating), as determined in paragraph (b)(3)(i)(D) of this section, divided by the represented value of SHORE, in Btu's per watt-hour, as determined in paragraph (b)(3)(ii) of this section;

(B) The representative average use cycle for heating of 972 hours per year;

(C) The adjustment factor of 1.15 (for heat pumps that are not variable speed) or 1.07 (for heat pumps that are variable speed), which serves to adjust the calculated design heating requirement and heating load hours to the actual load experienced by a heating system;

(D) A conversion factor of 0.001 kilowatt per watt; and

(E) The representative average unit cost of electricity in dollars per kilowatt-hour as provided pursuant to section 323(b)(2) of the Act;

(3) *Annual Operating Cost—Total.* Determine the represented value of estimated annual operating cost for air-source heat pumps that provide both heating and cooling by calculating the sum of the quantity determined in paragraph (f)(1) of this section added to the quantity determined in paragraph (f)(2) of this section.

(4) *Regional Annual Operating Cost—Cooling.* Determine the represented value of estimated regional annual operating cost for cooling-only units or the cooling portion of the estimated regional annual operating cost for air-source heat pumps that provide both heating and cooling as follows:

(i) When using appendix M1 to subpart B of part 430, the product of:

(A) The quotient of the represented value of cooling capacity, in Btu's per hour as determined in paragraph (b)(3)(iii) of this section, and multiplied by 0.93 for variable speed heat pumps only, divided by the represented value of SEER2, in Btu's per watt-hour, as determined in paragraph (b)(3)(ii) of this section;

(B) The estimated number of regional cooling load hours per year determined from the following table:

TABLE 4 TO PARAGRAPH (f)(4)(i)(B)

Climatic region	Regional cooling load hours
I	2,400
II	1,800
III	1,200
IV	800
V	400
VI	200

(C) A conversion factor of 0.001 kilowatts per watt; and

(D) The representative average unit cost of electricity in dollars per kilowatt-hour as provided pursuant to section 323(b)(2) of the Act.

(ii) When using appendix M2 to subpart B of part 430, regional annual operating cost for cooling-only units or the cooling portion of the estimated regional annual operating cost air-source heat pumps that provide both heating and cooling, does not apply.

(5) *Regional Annual Operating Cost—Heating.* Determine the represented value of estimated regional annual operating cost for air-source heat pumps that provide only heating or for the heating portion of the estimated regional annual operating cost for air-source heat pumps that provide both heating and cooling as follows:

(i) When using appendix M1 to subpart B of part 430, the product of:

(A) The estimated number of regional heating load hours per year determined from the following table:

TABLE 5 TO PARAGRAPH (f)(5)(i)(A)

Climatic region	Regional heating load hours
I	493
II	857
III	1,247
IV	1,701
V	2,202
VI	1,842

(B) The quotient of the represented value of cooling capacity (for air-source heat pumps that provide both cooling and heating) in Btu's per hour, as determined in paragraph (b)(3)(i)(C) of this section, or the represented value of heating capacity (for air-source heat pumps that provide only heating), as determined in paragraph (b)(3)(i)(D) of this section, divided by the represented value of HSPF2, in Btu's per watt-hour, calculated for the appropriate generalized climatic region of interest, and determined in paragraph (b)(3)(i)(B) of this section;

(C) The adjustment factor of 1.15 (for heat pumps that are not variable speed) or 1.07 (for heat pumps that are variable speed), which serves to adjust the calculated design heating requirement and heating load hours to the actual load experienced by a heating system;

(D) A conversion factor of 0.001 kilowatts per watt; and

(E) The representative average unit cost of electricity in dollars per kilowatt-hour as provided pursuant to section 323(b)(2) of the Act.

(ii) When using appendix M2 to subpart B of part 430, regional annual operating cost for air-source heat pumps that provide only heating or for the heating portion, does not apply.

(6) *Regional Annual Operating Cost—Total.* For air-source heat pumps that provide both heating and cooling, the estimated regional annual operating cost is the sum of the quantity determined in paragraph (f)(4) of this section added to the quantity determined in paragraph (f)(5) of this section.

(7) *Annual Operating Cost—Rounding.* Round any represented values of estimated annual operating cost determined in paragraphs (f)(1) through (6) of this section to the nearest dollar per year.

■ 4. Amend § 429.70 by revising paragraphs (e)(1) and (e)(2)(i)(A) to read as follows:

§ 429.70 Alternative methods for determining energy efficiency and energy use.

* * * * *

(e) * * *

(1) *Criteria an AEDM must satisfy.* A manufacturer may not apply an AEDM to an individual model/combination to determine its represented values (SEER2, EER2, HSPF2, SCORE, SHORE and/or $P_{W,OFF}$) pursuant to this section unless authorized pursuant to § 429.16(d) and:

(i) The AEDM is derived from a mathematical model that estimates the energy efficiency or energy consumption characteristics of the individual model or combination (SEER2, EER2, HSPF2, SCORE, SHORE and/or $P_{W,OFF}$) as measured by the applicable DOE test procedure; and

(ii) The manufacturer has validated the AEDM in accordance with paragraph (e)(2) of this section.

(2) * * *

(i) * * *

(A) *Minimum testing.* The manufacturer must test each basic model as required under § 429.16(b)(2).

* * * * *

■ 5. Amend § 429.134 by revising paragraph (k) to read as follows:

§ 429.134 Product-specific enforcement provisions.

* * * * *

(k) *Central air conditioners and heat pumps*—Before [*Date 180 days after publication of the final rule in the* **Federal Register**], the provisions in this section of this title as it appeared in the 10 CFR parts 200–499 edition revised as of January 1, 2023 are applicable. On and after [*Date 180 days after publication of the final rule in the* **Federal Register**], the following provisions apply.

(1) Verification of cooling capacity. The cooling capacity of each tested unit of the individual model (for single-package systems) or individual combination (for split systems) will be measured pursuant to the test requirements of § 430.23(m) of this chapter. The mean of the measurement(s) (either the measured cooling capacity for a single unit sample or the average of the measured cooling capacities for a multiple unit sample) will be used to determine the applicable standards for purposes of compliance.

(2) *Verification of C_D value.* (i) For central air conditioners and heat pumps other than models of outdoor units with no match, if manufacturers certify that they did not conduct the optional tests to determine the C_D^c and/or C_D^h value for an individual model (for single-package systems) or individual

combination (for split systems), as applicable, for each unit tested, the default C_D^c and/or C_D^h value will be used as the basis for the calculation of SEER2 or HSPF2 when testing in accordance with appendix M1 to subpart B of part 430, or SCORE or SHORE when testing in accordance with appendix M2 to subpart B of part 430. If manufacturers certify that they conducted the optional tests to determine the C_D^c and/or C_D^h value for an individual model (for single-package systems) or individual combination (for split systems), as applicable, the following provisions apply.

(A) If testing in accordance with appendix M1 to subpart B of part 430, the C_D^c and/or C_D^h value will be measured for each unit tested pursuant to appendix M1 to subpart B of part 430 and the result for each unit tested (either the tested value or the default value, as selected according to the criteria for the cyclic test in section E17 of AHRI 210/240–202X (incorporated by reference, see § 429.4)) will be used as the basis for calculation of SEER2 or HSPF2.

(B) If testing in accordance with appendix M2 to subpart B of part 430, the C_D^c and/or C_D^h value will be measured for each unit tested pursuant to appendix M2 to subpart B of part 430 and the result for each unit tested (either the tested value or the default value, as selected according to the criteria for the cyclic test in section E17 of AHRI 1600–202X (incorporated by reference, see § 429.4)) will be used as the basis for calculation of SCORE or SHORE.

(ii) For models of outdoor units with no match, DOE will use the default C_D^c and/or C_D^h pursuant to appendix M1 to subpart B of part 430 or appendix M2 to subpart B of part 430, as applicable.

(3) *Verification of cut-out and cut-in temperatures for central heat pumps.* (i) When testing in accordance with appendix M1 to subpart B of part 430, the cut-out and cut-in temperatures may be verified using the method in appendix J of AHRI 210/240–202X (incorporated by reference, see § 429.4). If this method is conducted, the tested $T_{OFF,T}$ and $T_{ON,T}$ values determined in the test shall be used as the cut-out and cut-in temperatures, respectively, to calculate HSPF2.

(ii) When testing in accordance with appendix M2 to subpart B of part 430, the cut-out and cut-in temperatures may be verified using the method in appendix J of AHRI 1600–202X (incorporated by reference, see § 429.4). If this method is conducted, the tested $T_{OFF,T}$ and $T_{ON,T}$ values determined in the test shall be used as the cut-out and cut-in temperatures, respectively, to calculate SHORE.

(4) *Verification of Variable Capacity Operation and of Fixed Settings for the Compressor and the Indoor Fan when Testing Variable Capacity Compressor Systems*—(i) *Conducting the Controls Verification Procedure.* A controls verification procedure (CVP) may be performed for any model certified as a variable capacity compressor system for the purposes of assessment or enforcement testing conducted according to appendix M1 to subpart B of part 430 or appendix M2 to subpart B of part 430 (*i.e.,* the certification tests), as applicable. For a heat pump, either a cooling mode CVP, a heating mode CVP, or both may be conducted, as elected by DOE. If a CVP is not conducted, the override instructions for the compressor and indoor fan, as specified by the manufacturer, will be used to conduct the tests per appendix M1 to subpart B of part 430 or, appendix M2 to subpart B of part 430, as applicable.

(A) *When testing in accordance with appendix M1 to subpart B of part 430.* The CVP will be conducted per appendix I of AHRI 210/240–202X (incorporated by reference, see § 429.4).

(B) *When testing in accordance with appendix M2 to subpart B of part 430.* The CVP will be conducted per appendix I of AHRI 1600–202X (incorporated by reference, see § 429.4).

(C) For systems determined to be variable capacity certified, single capacity systems as described in paragraph (k)(4)(ii)(B) of this section, the CVP cooling and heating minimum intervals may be omitted.

(ii) *Variable Capacity Determination.*(A) If the unit tested does meet the definition of a variable capacity compressor system based on performance of the CVP per paragraph (k)(4)(i)(A) or paragraph (k)(4)(i)(B) of this section, the efficiency metrics (SEER2, HSPF2, EER2, SCORE, SHORE, as applicable) shall be determined using the certification test applicable to variable capacity compressor systems.

(B) If the unit tested does not meet the definition of a variable capacity compressor system based on performance of the CVP per paragraph (k)(4)(i)(A) or paragraph (k)(4)(i)(B) of this section, and the tested unit is instead determined to be a variable capacity certified, single capacity system, the efficiency metrics (SEER2, HSPF2, EER2, SCORE, SHORE, as applicable) shall be determined using the certification test applicable to variable capacity certified, single capacity systems.

(C) If the unit tested does not meet the definition of a variable capacity compressor system based on performance of the CVP per paragraph (k)(4)(i)(A) or paragraph (k)(4)(i)(B) of this section, and the tested unit is instead determined to be a variable capacity certified, two capacity system, the efficiency metrics (SEER2, HSPF2, EER2, SCORE, SHORE, as applicable) shall be determined using the certification test applicable to variable capacity certified, two capacity systems.

(D) If, for a heat pump, a CVP is conducted for just one of the operating modes (heating or cooling), the system classifications for both modes will be based on the results of the one CVP conducted.

(iii) *CVP Tolerance Evaluation for Full and Minimum Load Intervals.*

(A) The data collected in the CVP per paragraph (k)(4)(i)(A) or paragraph (k)(4)(i)(B) of this section shall be evaluated for the duration of the individual CVP full or minimum load interval excluding the preliminary 30 minutes of equilibrium data, to determine compliance with test condition tolerances and test operating tolerances listed in section I5.1 of appendix I of AHRI 210/240–202X (incorporated by reference, see § 429.4) (if testing in accordance with appendix M1); or of AHRI 1600–202X (incorporated by reference, see § 429.4) (if testing in accordance with appendix M2).

(1) If the specified tolerances are met under system operation for 60 minutes, the average capacity and average power measured over this 60-minute test interval shall be recorded.

(2) If the four-hour time limit is reached by the system without maintaining the tolerances for a 60-minute period, but two successive test period sub-intervals are identified, each a minimum of 30 minutes, and comprised of a whole number of compressor cycles (either compressor on-off cycles or speed/capacity cycles) or in which minimal fluctuations of the compressor speed/capacity level are observed, where both the time averaged integrated capacity and time averaged integrated power for the full 60 minutes of the two periods are observed to be within two percent of each other, a single capacity average and a single power average shall be recorded, both averaged over compressor-on periods of the two 60-minute sub-intervals. These average capacity and power values shall be considered the capacity and power values recorded for the test interval.

(3) If the four-hour time limit is reached by the system without complying with either paragraph (k)(4)(iii)(A)*(1)* or (k)(4)(iii)(B)*(2)* of this section, the time averaged integrated

capacity and time averaged integrated power shall be recorded for only the compressor-on periods over the final 120 minutes of the test interval.

(B) The measured capacity for each full load interval, as evaluated per the CVP conducted in paragraph (k)(4)(i)(A) or paragraph (k)(4)(i)(B) of this section, shall agree with the corresponding certification test within 6%, as follows:

$$\text{Cooling full: } \frac{\dot{q}_{A,Full} - \dot{q}_{CVP,A,Full}}{\dot{q}_{A,Full}} \times 100 \leq 6.0$$

$$\text{Heating full (17°F): } \frac{\dot{q}_{H3,Full} - \dot{q}_{CVP,H(17)}}{\dot{q}_{H3,Full}} \times 100 \leq 6.0$$

$$\text{Heating full (5°F): } \frac{\dot{q}_{H4,Full} - \dot{q}_{CVP,H(5)}}{\dot{q}_{H4,Full}} \times 100 \leq 6.0$$

(C) The measured capacity for each minimum load interval, as evaluated per the CVP conducted in paragraph (k)(4)(i)(A) or paragraph (k)(4)(i)(B) of this section, shall agree with the corresponding certification test within 6% of the cooling or heating mode full load certification test capacity, as follows:

$$\text{Cooling minimum: } \frac{\dot{q}_{CVP,F,Low} - \dot{q}_{F,Low}}{\dot{q}_{A,Full}} \times 100 \leq 6.0$$

$$\text{Heating minimum: } \frac{\dot{q}_{CVP,H(47)} - \dot{q}_{H1,Low}}{\dot{q}_{H3,Full}} \times 100 \leq 6.0$$

(D) The measured efficiency for the full and minimum load interval, as evaluated per the CVP conducted in paragraph (k)(4)(i)(A) or paragraph (k)(4)(i)(B) of this section, shall agree with the corresponding certification test within 10%, as follows:

$$\text{Cooling full: } \frac{EER2_{A,Full} - EER2_{CVP,A,Full}}{EER2_{A,Full}} \times 100 \leq 10.0$$

$$\text{Cooling minimum: } \frac{EER_{F,Low} - EER_{CVP,F,Low}}{EER_{F,Low}} \times 100 \leq 10.0$$

$$\text{Heating full (5°F): } \frac{COP_{H4,Full} - COP_{CVP,H(5)}}{COP2_{H4,Full}} \times 100 \leq 10.0$$

$$\text{Heating full (17°F): } \frac{COP_{H3,Full} - COP_{CVP,H(17)}}{COP_{H3,Full}} \times 100 \leq 10.0$$

$$\text{Heating minimum: } \frac{COP_{H1,Low} - COP_{CVP,H(47)}}{COP_{H1,Low}} \times 100 \leq 10.0$$

(iv) *Evaluation of results when CVP tolerances are met.* If the tolerances for capacity and efficiency are met by the applicable full and minimum load intervals as per paragraphs (k)(4)(iii)(B), (k)(4)(iii)(C) and (k)(4)(iii)(D) of this section, the certified override instructions for the compressor and indoor fan, as specified by the manufacturer, shall be deemed valid, and the efficiency metrics (SEER2, HSPF2, EER2, SCORE, SHORE, as applicable), shall be determined based on these certification tests with no adjustments determined based on the CVP results.

(v) *Evaluation of results when CVP tolerances are not met.* If the tolerances for capacity and efficiency are not met by the applicable full and minimum load intervals as per paragraphs (k)(4)(iii)(B), (k)(4)(iii)(C) and (k)(4)(iii)(D) of this section, the unit shall be tested per instructions in paragraphs (k)(4)(v)(A) to (k)(4)(v)(C) of this section, as applicable. The instructions in paragraphs (k)(4)(v)(A) to (k)(4)(v)(C) of this section shall be followed, as applicable, only for the certification tests corresponding to the

failed compressor speed interval based on the evaluations of paragraphs (k)(4)(iii)(B), (k)(4)(iii)(C) and (k)(4)(iii)(D) of this section. For all compressor speed intervals for which the capacity and EER/COP are in tolerance as per paragraphs (k)(4)(iii)(B), (k)(4)(iii)(C) and (k)(4)(iii)(D) of this section, the corresponding certification tests shall be used without adjustments.

(A) The instructions of this paragraph shall be applied to systems for which the same control device used as per the CVP conducted in paragraph (k)(4)(i)(A) or paragraph (k)(4)(i)(B) of this section is used as the means for overriding the controls, and both (a) monitoring of the compressor and indoor blower speed during native-control operation without otherwise impacting the control of the system, and (b) monitoring and adjustment of the compressor and indoor blower speed during certification tests, where monitoring and adjustment means the control device has the ability to display and make discrete adjustments, as required, to the compressor and indoor blower speeds without additional hardware or non-publicly available software, is supported by the control device. The compressor and indoor blower speed shall be monitored during the CVP conducted in paragraph (k)(4)(i)(A) or paragraph (k)(4)(i)(B) of this section. The average compressor and indoor blower speeds and indoor air volume rate shall be evaluated for the same time period(s) used as described in paragraph (k)(4)(iii)(A) to determine average capacity and power for the CVP test. The compressor speed for the certification test shall be set at this average value observed during the corresponding CVP test interval. The indoor blower speed shall be set as described in section 6.1.5 of AHRI 210/240–202X (incorporated by reference, see § 429.4) (if testing in accordance with appendix M1); or of AHRI 1600–202X (incorporated by reference, see § 429.4) (if testing in accordance with appendix M2), except the ''specified airflow'' shall be set as the average value observed during the corresponding CVP test interval. The same adjusted compressor speed shall be used for the other certification tests that require the same speed, as applicable, as detailed in the following table. Specifically, for each of the CVP tests listed in the first column for which either the capacity tolerances of paragraph (k)(4)(iii)(B) or paragraph (k)(4)(iii)(C) of this section are not met or the efficiency tolerances of paragraph (k)(4)(iii)(D) are not met, the certification tests to be conducted again using the compressor speed determined in the corresponding CVP test are listed in the last three columns of the table, depending on which of the three kinds of system the model is designated. If required, the adjusted $\dot{q}_{H3,Full}$ and $P_{H3,Full}$ shall be used to calculate $\dot{q}^{k=2}{}_{hcalc}$ (47) and $P^{k=2}{}_{hcalc}$ (47), respectively, to represent performance at 47 °F as described in section 11.2.2.4 of AHRI 210/240–202X (incorporated by reference, see § 429.4) (if testing in accordance with appendix M1), or of AHRI 1600–202X (incorporated by reference, see § 429.4) (if testing in accordance with appendix M2), and for use in calculating performance at 35 °F. If required, the adjusted $H_{1,Low}$ and $H_{3,Low}$ tests shall be used to calculate $\dot{q}_{thi,H2,Low}$ and $P_{H2,Low}$, respectively, as described in section 6.1.3.4 of AHRI 210/240–202X (incorporated by reference, see § 429.4) (if testing in accordance with appendix M1), or of AHRI 1600–202X (incorporated by reference, see § 429.4) (if testing in accordance with appendix M2). No adjustments are required for intermediate or nominal compressor speed tests or, if cyclic tests are conducted, for the degradation coefficient(s).

TABLE 1 TO PARAGRAPH (k)(4)(v)(A)

CVP Test	Certification Tests that use the Indicated CVP Test Compressor Speed or would have certification test results adjusted per Paragraph (k)(4)(v)(B) of this section, if the CVP Test is out of Capacity or EER/COP Tolerance per Paragraph (k)(4)(iii) of this section		
	Variable capacity certified, single capacity system	Variable capacity certified, two capacity system	Variable capacity system
A_{full}	A_{Full}, B_{Full}	A_{Full}, B_{Full}	A_{Full}, B_{Full}.
F_{low}	N/A	B_{Low}, F_{Low}	B_{Low}, F_{Low}.
$H_{1,low}$	N/A	$H_{0,Low}$, $H_{1,Low}$, $H_{3,Low}$	$H_{0,Low}$, $H_{1,Low}$.
$H_{3,full}$	$H_{2,Full}$, $H_{3,Full}$	$H_{3,Full}$	$H_{3,Full}$.
$H_{4,Full}$	$H_{4,Full}$	$H_{4,Full}$	$H_{4,Full}$.

(B) The instructions of this paragraph shall be applied to systems for which the means for overriding the compressor and indoor blower speed as discussed in paragraph (k)(4)(v)(A) of this section is not provided by the control used for conducting the CVP. For each of the CVP tests listed in the first column of Table 1 of this section for which either the capacity tolerances of paragraph (k)(4)(iii)(B) or paragraph (k)(4)(iii)(C) of this section are not met or the efficiency tolerances of paragraph (k)(4)(iii)(D) are not met, depending on which of the three kinds of system the model is designated, the certification test results to be adjusted based on the results of the CVP test are indicated by the last three columns of the table for each CVP test listed in the first column. The average capacities and power(s) measured during the CVP time period(s) described in paragraph (k)(4)(iii)(A) of this section shall be used. For the certification tests requiring adjustment with no CVP interval (any required certification test other than A_{full}, F_{low}, $H1_{low}$, $H3_{full}$ and $H4_{full}$), the capacity and power shall be adjusted. The capacity shall be adjusted by applying the ratio of the capacity measured during the CVP test interval divided by the capacity measured during the certification test (for the corresponding CVP interval). The power shall be adjusted by applying the ratio of the efficiency measured during the CVP test interval divided by the efficiency measured during the certification test (for the corresponding CVP interval), as follows:

Cooling full capacity:

$$\dot{q}_{B,Full} = \dot{q}_{B,Full,Certification} \times \frac{\dot{q}_{CVP,A,Full}}{\dot{q}_{A,Full,Certification}}$$

Cooling full power:

$$P_{B,Full} = P_{B,Full,Certification} \times \frac{EER2_{A,Full,Certification}}{EER2_{CVP,A,Full}}$$

Cooling minimum capacity:

$$\dot{q}_{B,Low} = \dot{q}_{B,Low,Certification} \times \frac{\dot{q}_{CVP,F,Low}}{\dot{q}_{F,Low,Certification}}$$

Cooling minimum power:

$$P_{B,Low} = P_{B,Low,Certification} \times \frac{EER_{F,Low,Certification}}{EER_{CVP,F,Low}}$$

Heating minimum capacity:

$$\dot{q}_{H0,Low} = \dot{q}_{H0,Low,Certification} \times \frac{\dot{q}_{CVP,H1,Low}}{\dot{q}_{H1,Low,Certification}}$$

$$\dot{q}_{H3,Low} = \frac{\dot{q}_{CVP,H1,Low}}{(1 + 30 \cdot CSF)}$$

Heating minimum power:

$$P_{H0,Low} = P_{H0,Low,Certification} \times \frac{COP_{H1,Low,Certification}}{COP_{CVP,H1,Low}}$$

$$P_{H3,Low} = \frac{P_{CVP,H1,Low}}{(1 + 30 \cdot PSF)}$$

Where:

CSF = 0.0204/°F, capacity slope factor for Split Systems

CSF = 0.0262/°F, capacity slope factor for Single Package Units

PSF = 0.00455/°F, power slope factor for all products

(C) If required, the measured $Q_{H3,Full}$ and $E_{H3,Full}$ from the CVP shall be used to calculate $\dot{q}^{k=2}{}_{hcalc}$(47) and $P^{k=2}{}_{hcalc}$ (47), respectively, to represent performance at 47 °F as described in section 11.2.2.4 of AHRI 210/240–202X (incorporated by reference, see § 429.4) (if testing in accordance with appendix M1), or of AHRI 1600–202X (incorporated by reference, see § 429.4) (if testing in accordance with appendix M2), and for use in calculating performance at 35 °F. If required, the measured $H_{1,Low}$ from the CVP and the adjusted $H_{3,Low}$ tests shall be used to calculate $\dot{q}_{thi,H2,Low}$ and $P_{H2,Low}$, respectively, as described in section 6.1.3.4 of AHRI 210/240–202X (incorporated by reference, see § 429.4) (if testing in accordance with appendix M1) or of AHRI 1600–202X (incorporated by reference, see § 429.4) (if testing in accordance with appendix M2). No adjustments are required for intermediate or nominal compressor speed tests or, if cyclic tests are conducted, the degradation coefficient(s).

(D) If the test unit is determined to be variable capacity certified, single capacity system, or variable capacity certified, two capacity system and is not certified or marketed for use with only a proprietary control device, the same simulated thermostat low voltage signal that resulted in full speed compressor operation for the full load intervals shall be used for all certification full load tests. If the test unit is determined to be variable capacity certified, two capacity system, the same simulated thermostat low voltage signal that resulted in low-speed compressor operation for the low load intervals shall be used for all certification low load tests.

* * * * *

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 6. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 7. Amend § 430.3 by revising paragraphs (b)(4), (c) and (g) to read as follows:

§ 430.3 Materials incorporated by reference.

* * * * *

(b) * * *

(4) ANSI/AMCA 210–07, ANSI/ASHRAE 51–07 (''AMCA 210–2007''), Laboratory Methods of Testing Fans for Certified Aerodynamic Performance

Rating, ANSI approved August 17, 2007, Section 8—Report and Results of Test, Section 8.2—Performance graphical representation of test results, IBR approved for appendix M to subpart B, as follows:

(i) Figure 2A—Static Pressure Tap, and

(ii) Figure 12—Outlet Chamber Setup—Multiple Nozzles in Chamber.

* * * * *

(c) *AHRI.* Air-Conditioning, Heating, and Refrigeration Institute, 2111 Wilson Blvd., Suite 500, Arlington, VA 22201, 703–524–8800, or go to *https://www.ahrinet.org.*

(1) ANSI/AHRI 210/240–2008 with Addenda 1 and 2 (''AHRI 210/240–2008''), 2008 Standard for Performance Rating of Unitary Air-Conditioning & Air-Source Heat Pump Equipment, ANSI approved October 27, 2011 (Addendum 1 dated June 2011 and Addendum 2 dated March 2012), IBR approved for appendix M to subpart B, as follows:

(i) Section 6—Rating Requirements, Section 6.1—Standard Ratings, 6.1.3—Standard Rating Tests, 6.1.3.2—Electrical Conditions;

(ii) Section 6—Rating Requirements, Section 6.1—Standard Ratings, 6.1.3—Standard Rating Tests, 6.1.3.4—Outdoor-Coil Airflow Rate;

(iii) Section 6—Rating Requirements, Section 6.1—Standard Ratings, 6.1.3—Standard Rating Tests, 6.1.3.5—Requirements for Separated Assemblies;

(iv) Figure D1—Tunnel Air Enthalpy Test Method Arrangement;

(v) Figure D2—Loop Air Enthalpy Test Method Arrangement; and

(vi) Figure D4—Room Air Enthalpy Test Method Arrangement.

(2) AHRI Standard 210/240–202X (''AHRI 210/240–202X''), *202X Standard for Performance Rating of Unitary Air-Conditioning & Air-Source Heat Pump Equipment* [version and date TBD]; IBR approved for appendix M1 to subpart B.

(3) AHRI Standard 1160–2009 (''AHRI 1160''), Performance Rating of Heat Pump Pool Heaters, 2009, IBR approved for appendix P to subpart B.

(4) ANSI/AHRI 1230–2010 with Addendum 2 (''AHRI 1230–2010''), 2010 Standard for Performance Rating of Variable Refrigerant Flow (VRF) Multi-Split Air-Conditioning and Heat Pump Equipment (including Addendum 1 dated March 2011), ANSI approved August 2, 2010 (Addendum 2 dated June 2014), IBR approved for appendix M to subpart B, as follows:

(i) Section 3—Definitions (except 3.8, 3.9, 3.13, 3.14, 3.15, 3.16, 3.23, 3.24, 3.26, 3.27, 3.28, 3.29, 3.30, and 3.31);

(ii) Section 5—Test Requirements, Section 5.1 (untitled), 5.1.3–5.1.4;

(iii) Section 6—Rating Requirements, Section 6.1—Standard Ratings, 6.1.5—Airflow Requirements for Systems with Capacities <65,000 Btu/h [19,000 W];

(iv) Section 6—Rating Requirements, Section 6.1—Standard Ratings, 6.1.6—Outdoor-Coil Airflow Rate (Applies to all Air-to-Air Systems);

(v) Section 6—Rating Requirements, Section 6.2—Conditions for Standard Rating Test for Air-cooled Systems < 65,000 Btu/h [19,000W] (except Table 8); and

(vi) Table 4—Refrigerant Line Length Correction Factors.

(5) AHRI 1600–202X (''AHRI 1600–202X''), *202X Standard for Performance Rating of Unitary Air-Conditioning & Air-Source Heat Pump Equipment,* [version and date TBD]; IBR approved for appendix M2 to subpart B.

* * * * *

(g) *ASHRAE.* American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc., 180 Technology Parkway NW, Peachtree Corners, GA 30092; (800) 527–4723 or (404) 636–8400; *www.ashrae.org.*

(1) ANSI/ASHRAE Standard 16–2016 (''ANSI/ASHRAE 16''), *Method of Testing for Rating Room Air Conditioners, Packaged Terminal Air Conditioners, and Packaged Terminal Heat Pumps for Cooling and Heating Capacity,* ANSI approved November 1, 2016; IBR approved for appendices F, M1, and M2 to subpart B.

(2) ANSI/ASHRAE 23.1–2010, (''ASHRAE 23.1–2010''), Methods of Testing for Rating the Performance of Positive Displacement Refrigerant Compressors and Condensing Units that Operate at Subcritical Temperatures of the Refrigerant, ANSI approved January 28, 2010, IBR approved for appendix M to subpart B, as follows:

(i) Section 5—Requirements;

(ii) Section 6—Instruments;

(iii) Section 7—Methods of Testing; and

(iv) Section 8—Compressor Testing.

(3) ANSI/ASHRAE Standard 37–2009, (''ASHRAE 37–2009''), *Methods of Testing for Rating Electrically Driven Unitary Air-Conditioning and Heat Pump Equipment,* ANSI approved June 25, 2009, IBR approved for appendices M1, M2, AA, CC, and CC1 to subpart B.

(4) ANSI/ASHRAE Standard 37–2009, (''ANSI/ASHRAE 37–2009''), *Methods of Testing for Rating Electrically Driven Unitary Air-Conditioning and Heat Pump Equipment,* ANSI approved June 25, 2009, IBR approved for appendix M to subpart B, as follows:

(i) Section 5—Instruments, Section 5.1—Temperature Measuring Instruments: 5.1.1;

(ii) Section 5—Instruments, Section 5.2—Refrigerant, Liquid, and Barometric Pressure Measuring Instruments;

(iii) Section 5—Instruments, Section 5.5—Volatile Refrigerant Flow Measurement;

(iv) Section 6—Airflow and Air Differential Pressure Measurement Apparatus, Section 6.1—Enthalpy Apparatus (Excluding Figure 3): 6.1.1–6.1.2 and 6.1.4;

(v) Section 6—Airflow and Air Differential Pressure Measurement Apparatus, Section 6.2—Nozzle Airflow Measuring Apparatus (Excluding Figure 5);

(vi) Section 6—Airflow and Air Differential Pressure Measurement Apparatus, Section 6.3—Nozzles (Excluding Figure 6);

(vii) Section 6—Airflow and Air Differential Pressure Measurement Apparatus, Section 6.4—External Static Pressure Measurements;

(viii) Section 6—Airflow and Air Differential Pressure Measurement Apparatus, Section 6.5—Recommended Practices for Static Pressure Measurements;

(ix) Section 7—Methods of Testing and Calculation, Section 7.3—Indoor and Outdoor Air Enthalpy Methods (Excluding Table 1);

(x) Section 7—Methods of Testing and Calculation, Section 7.4—Compressor Calibration Method;

(xi) Section 7—Methods of Testing and Calculation, Section 7.5—Refrigerant Enthalpy Method;

(xii) Section 7—Methods of Testing and Calculation, Section 7.7—Airflow Rate Measurement, Section 7.7.2—Calculations—Nozzle Airflow Measuring Apparatus (Excluding Figure 10), 7.7.2.1–7.7.2.2;

(xiii) Section 8—Test Procedures, Section 8.1—Test Room Requirements: 8.1.2–8.1.3;

(xiv) Section 8—Test Procedures, Section 8.2—Equipment Installation;

(xv) Section 8—Test Procedures, Section 8.6—Additional Requirements for the Outdoor Air Enthalpy Method, Section 8.6.2;

(xvii) Section 8—Test Procedures, Section 8.6—Additional Requirements for the Outdoor Air Enthalpy Method, Table 2a—Test Tolerances (SI Units), and

(xviii) Section 8—Test Procedures, Section 8.6—Additional Requirements for the Outdoor Air Enthalpy Method, Table 2b—Test Tolerances (I–P Units);

(xix) Section 9—Data to be Recorded, Section 9.2—Test Tolerances; and

(xx) Section 9—Data to be Recorded, Table 3—Data to be Recorded.

(5) ASHRAE 41.1–1986 (Reaffirmed 2006) (''ASHRAE 41.1–1986''), *Standard Method for Temperature Measurement,* approved February 18, 1987; IBR approved for appendices AA, CC, and CC1 to subpart B.

(6) ANSI/ASHRAE 41.1–2013 (''ANSI/ASHRAE 41.1''), *Standard Method for Temperature Measurement,* ANSI approved January 30, 2013; IBR approved for appendices F and X1 to subpart B.

(7) ANSI/ASHRAE Standard 41.1–2013, (''ANSI/ASHRAE 41.1–2013''), *Standard Method for Temperature Measurement,* ANSI approved January 30, 2013, IBR approved for appendix M to subpart B, as follows:

(i) Section 4—Classifications;

(ii) Section 5—Requirements, Section 5.3—Airstream Temperature Measurements;

(iii) Section 6—Instruments; and

(iv) Section 7—Temperature Test Methods (Informative).

(8) ANSI/ASHRAE Standard 41.1–2020 (''ASHRAE 41.1–2020''), *Standard Methods for Temperature Measurement,* ANSI-approved June 30, 2020; IBR approved for appendix E to subpart B.

(9) ANSI/ASHRAE Standard 41.2–1987 (RA 92), (''ASHRAE 41.2–1987 (RA 1992)''), *Standard Methods for Laboratory Airflow Measurement,* ANSI reaffirmed April 20, 1992; IBR approved for appendix F to subpart B.

(10) ANSI/ASHRAE Standard 41.2–1987 (RA 1992), (''ASHRAE 41.2–1987 (RA 1992)''), *Standard Methods for Laboratory Airflow Measurement,* ANSI reaffirmed April 20, 1992, Section 5—Section of Airflow-Measuring Equipment and Systems, IBR approved for appendix M to subpart B, as follows:

(i) Section 5.2—Test Ducts, Section 5.2.2—Mixers, 5.2.2.1—Performance of Mixers (excluding Figures 11 and 12 and Table 1); and

(ii) Figure 14—Outlet Chamber Setup for Multiple Nozzles in Chamber.

(11) ANSI/ASHRAE Standard 41.3–2014, (''ASHRAE 41.3–2014''), *Standard Methods for Pressure Measurement,* ANSI approved July 3, 2014; IBR approved for appendix F to subpart B.

(12) ANSI/ASHRAE Standard 41.6–1994 (RA 2006) (''ASHRAE 41.6–1994''), *Standard Method for Measurement of Moist Air Properties,* ANSI-reaffirmed January 27, 2006; IBR approved for appendices CC and CC1 to subpart B.

(13) ANSI/ASHRAE Standard 41.6–2014, (''ASHRAE 41.6–2014''), *Standard Method for Humidity Measurement,* ANSI approved July 3, 2014; IBR approved for appendices E, F, and EE to subpart B.

(14) ANSI/ASHRAE Standard 41.6–2014, (''ASHRAE 41.6–2014''), *Standard Method for Humidity Measurement,* ANSI approved July 3, 2014, IBR approved for appendix M to subpart B, as follows:

(i) Section 4—Classifications;

(ii) Section 5—Requirements;

(iii) Section 6—Instruments and Calibration; and

(iv) Section 7—Humidity Measurement Methods.

(15) ANSI/ASHRAE 41.9–2011, (''ASHRAE 41.9–2011''), *Standard Methods for Volatile-Refrigerant Mass Flow Measurements Using Calorimeters,* ANSI approved February 3, 2011, IBR approved for appendix M to subpart B, as follows:

(i) Section 5—Requirements;

(ii) Section 6—Instruments;

(iii) Section 7—Secondary Refrigerant Calorimeter Method;

(iv) Section 8—Secondary Fluid Calorimeter Method;

(v) Section 9—Primary Refrigerant Calorimeter Method; and

(vi) Section 11—Lubrication Circulation Measurements.

(16) ANSI/ASHRAE Standard 41.11–2014, (''ASHRAE 41.11–2014''), *Standard Methods for Power Measurement,* ANSI approved July 3, 2014; IBR approved for appendix F to subpart B.

(17) ANSI/ASHRAE Standard 103–1993, (''ASHRAE 103–1993''), *Methods of Testing for Annual Fuel Utilization Efficiency of Residential Central Furnaces and Boilers,* (with Errata of October 24, 1996), except for sections 7.1, 7.2.2.2, 7.2.2.5, 7.2.3.1, 7.8, 8.2.1.3, 8.3.3.1, 8.4.1.1, 8.4.1.1.2, 8.4.1.2, 8.4.2.1.4, 8.4.2.1.6, 8.6.1.1, 8.7.2, 8.8.3, 9.1.2.2.1, 9.1.2.2.2, 9.5.1.1, 9.5.1.2.1, 9.5.1.2.2, 9.5.2.1, 9.7.1, 9.7.4, 9.7.6, 9.10, 11.5.11.1, 11.5.11.2 and appendices B and C, approved October 4, 1993; IBR approved for § 430.23 and appendix N to subpart B.

(18) ANSI/ASHRAE Standard 103–2007 (''ASHRAE 103–2007''), *Method of Testing for Annual Fuel Utilization Efficiency of Residential Central Furnaces and Boilers,* ANSI-approved March 25, 2008; IBR approved for appendix AA to subpart B.

(19) ANSI/ASHRAE Standard 103–2017 (''ASHRAE 103–2017''), *Method of Testing for Annual Fuel Utilization Efficiency of Residential Central Furnaces and Boilers,* ANSI-approved July 3, 2017; IBR approved for § 430.23 and appendices O and EE to subpart B.

(20) ANSI/ASHRAE Standard 116–2010, (''ASHRAE 116–2010''), *Methods of Testing for Rating Seasonal Efficiency of Unitary Air Conditioners and Heat Pumps,* ANSI approved February 24, 2010, Section 7—Methods of Test, Section 7.4—Air Enthalpy Method—Indoor Side (Primary Method), Section 7.4.3—Measurements, Section 7.4.3.4—Temperature, Section 7.4.3.4.5, IBR approved for appendix M to subpart B.

(21) ANSI/ASHRAE Standard 116–2010, (''ASHRAE 116–2010''), *Methods of Testing for Rating Seasonal Efficiency of Unitary Air Conditioners and Heat Pumps,* ANSI approved February 24, 2010; IBR approved for appendices M1 and M2 to subpart B.

(22) ANSI/ASHRAE Standard 118.2–2022 (''ASHRAE 118.2–2022''), *Method of Testing for Rating Residential Water Heaters and Residential-Duty Commercial Water Heaters,* ANSI-approved March 1, 2022; IBR approved for appendix E to subpart B.

(23) ANSI/ASHRAE Standard 146–2011 (''ASHRAE 146''), *Method of Testing and Rating Pool Heaters,* ASHRAE approved February 2, 2011; IBR approved for appendix P to subpart B.

* * * * *

■ 8. Amend § 430.23 by revising paragraph (m) to read as follows:

§ 430.23 Test procedures for the measurement of energy and water consumption.

* * * * *

(m) *Central air conditioners and heat pumps.* See the note at the beginning of appendices M1 and M2 to this subpart to determine the appropriate test method. Determine all values discussed in this section using a single appendix.

(1) Determine cooling capacity from the steady-state wet-coil test (A or A_{full} Test), as per instructions in section 2 of appendix M1 or M2 to this subpart, and rounded off to the nearest:

(i) To the nearest 50 Btu/h if cooling capacity is less than 20,000 Btu/h;

(ii) To the nearest 100 Btu/h if cooling capacity is greater than or equal to 20,000 Btu/h but less than 38,000 Btu/h; and

(iii) To the nearest 250 Btu/h if cooling capacity is greater than or equal to 38,000 Btu/h and less than 65,000 Btu/h.

(2) Determine seasonal energy efficiency ratio 2 (SEER2) as described in sections 2 and 4 of appendix M1 to this subpart or seasonal cooling and off-mode rating efficiency (SCORE) as described in sections 2 and 3 of appendix M2 to this subpart, and round off to the nearest 0.025 Btu/W-h.

(3) Determine energy efficiency ratio 2 (EER2) as described in section 2 of appendix M1 or M2 to this subpart, and round off to the nearest 0.025 Btu/W-h. EER2 is the efficiency from the A or A_{full} test, whichever applies.

(4) Determine heating seasonal performance factor 2 (HSPF2) as

described in sections 2 and 4 of appendix M1 to this subpart or seasonal heating and off-mode rating efficiency (SHORE) as described in sections 2 and 3 of appendix M2 to this subpart, and round off to the nearest 0.025 Btu/W-h.

(5) Determine average off mode power consumption as described in section 3 of appendix M1 to this subpart, and round off to the nearest 0.5 W. Average off mode power consumption is not required when testing in accordance with appendix M2 to this subpart.

(6) Determine all other measures of energy efficiency or consumption or other useful measures of performance using appendix M1 or M2 of this subpart.

* * * * *

■ 9. Appendix M1 to subpart B of part 430 is revised to read as follows:

Appendix M1 to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Central Air Conditioners and Heat Pumps

Note: Prior to [*Date 180 days after publication of the final rule in the* **Federal Register**], representations with respect to the energy use or efficiency of central air conditioners and heat pumps, including compliance certifications, must be based on testing conducted in accordance with:

(a) Appendix M1 to this subpart, in the 10 CFR parts 200 through 499 edition revised as of January 1, 2023; or

(b) This appendix.

Beginning [*Date 180 days after publication of the final rule in the* **Federal Register**], and prior to the compliance date of amended standards for central air conditioners and heat pumps based on Seasonal Cooling and Off-mode Rating Efficiency (SCORE) and Seasonal Heating and Off-mode Rating Efficiency (SHORE), representations with respect to energy use or efficiency of central air conditioners and heat pumps, including compliance certifications, must be based on testing conducted in accordance with this appendix.

Beginning on the compliance date of amended standards for central air conditioners and heat pumps based on SCORE and SHORE, representations with respect to energy use or efficiency of central air conditioners and heat pumps, including compliance certifications, must be based on testing conducted in accordance with appendix M2 to this subpart.

Manufacturers may also certify compliance with any amended energy conservation standards for central air conditioners and heat pumps based on SCORE or SHORE prior to the applicable compliance date for those standards, and those compliance certifications must be based on testing in accordance with appendix M2 to this subpart.

1. Incorporation by Reference

In § 430.3, DOE incorporated by reference the entire standard for AHRI 210/240–202X, ANSI/ASHRAE 16–2016, ANSI/ASHRAE 37–2009 and ANSI/ASHRAE 116–2010. However, certain enumerated provisions of AHRI 210/240–202X, ANSI/ASHRAE 16–2016, ANSI/ASHRAE 37–2009 and ANSI/ASHRAE 116–2010, as set forth in sections 1.1 through 1.4 of this appendix, are inapplicable. To the extent there is a conflict between the terms or provisions of a referenced industry standard and the CFR, the CFR provisions control.

1.1 AHRI 210/240–202X

(a) Section 1 Purpose is inapplicable,

(b) Section 2 Scope is inapplicable,

(c) The following subsections of Section 3 Definitions are inapplicable: 3.2.15 (Double-duct system), 3.2.19 (Gross capacity), 3.2.47 (Oil Recovery Mode), 3.2.52 (Published Rating), 3.2.64 (Standard Filter), 3.2.79 (Unitary Air-conditioner), 3.2.80 (Unitary Heat Pump),

(d) Section 4 Classifications is inapplicable,

(e) The following subsections of Section 6 Rating Requirements are inapplicable: 6.1.8, 6.2, 6.3, 6.4 and 6.5,

(f) Section 7 Minimum Data Requirements for Published Ratings is inapplicable,

(g) Section 8 Operating Requirements is inapplicable,

(h) Section 9 Marking and Nameplate Data is inapplicable,

(i) Section 10 Conformance Conditions is inapplicable,

(j) Appendix A References—Normative is inapplicable,

(k) Appendix B References—Informative is inapplicable,

(l) Appendix C Secondary Capacity Check Requirements—Normative is inapplicable,

(m) Appendix F Unit Configurations for Standard Efficiency Determination—Normative is inapplicable,

(n) Appendix H Verification Testing—Normative is inapplicable,

(o) Appendix I Controls Verification Procedure—Normative is inapplicable, and

(p) Appendix J Determination of Cut in and Cut out temperatures—Normative is inapplicable,

1.2 ANSI/ASHRAE 37–2009

(a) Section 1—Purpose is inapplicable,

(b) Section 2—Scope is inapplicable, and

(c) Section 4—Classification is inapplicable.

1.3 ANSI/ASHRAE 16–2016

(a) Section 1—Purpose is inapplicable,

(b) Section 2—Scope is inapplicable, and

(c) Section 4—Classification is inapplicable.

1.4 ANSI/ASHRAE 116–2010

(a) Section 1—Purpose is inapplicable,

(b) Section 2—Scope is inapplicable,

(c) Section 4—Classification is inapplicable,

(d) Section 7—Methods of Test is inapplicable,

(e) References is inapplicable,

(f) Appendix A—Example Bin Calculations is inapplicable, and

(g) Appendix B—Bibliography is inapplicable.

2. General

Determine the cooling capacity, heating capacity, and applicable energy efficiency metrics (SEER2, HSPF2, and EER2) in accordance with the specified sections of AHRI 210/240–202X and the applicable provisions of ANSI/ASHRAE 16–2016, ANSI/ASHRAE 37–2009, and ANSI/ASHRAE 116–2010. The A_{Full} (cooling mode) and $H_{1,\ Full}$ or $H_{1,\ Nom}$ (heating mode, if applicable) shall have a secondary capacity check completed. For all other tests in each mode, it is permissible to not use a secondary capacity check.

Sections 3, 4, and 5 of this appendix provide additional instructions for testing. In cases where there is a conflict, the language of this appendix takes highest precedence, followed, in order, by: AHRI 210/240–202X, ANSI/ASHRAE 37–2009, ANSI/ASHRAE 16–2016 and ANSI/ASHRAE 116–2010. Any subsequent amendment to a referenced document by the standard-setting organization will not affect the test procedure in this appendix, unless and until the test procedure is amended by DOE. Material is incorporated as it exists on the date of the approval, and a notice of any change in the incorporation will be published in the **Federal Register**.

3. Off-Mode Power

Determine off-mode power, $P_{W,\ OFF}$, in accordance with section 11.3 and appendix G of AHRI 210/240–202X.

4. Outdoor Units With No Match (OUWNM)

4.1 Definition

An Outdoor Unit that is not distributed in commerce with any indoor units, that meets any of the following criteria:

(a) Is designed for use with a refrigerant that makes the unit banned for installation when paired with an Indoor Unit as a system, according to EPA regulations in 40 CFR chapter I, subchapter C,

(b) Is designed for use with a refrigerant that has a 95 °F midpoint saturation absolute pressure that is ±18 percent of the 95 °F saturation absolute pressure for R–22, or

(c) Is shipped without a specified refrigerant from the point of manufacture or is shipped such that more than two pounds of refrigerant are required to meet the charge per section 5.1.8 of AHRI 210/240–202X. This shall not apply if either:

(1) The factory charge is equal to or greater than 70% of the outdoor unit internal volume times the liquid density of refrigerant at 95 °F, or

(2) An A2L refrigerant is approved for use and listed in the certification report.

4.2 Testing

An OUWNM shall be tested with an indoor coil having nominal tube diameter of 0.375 in and an NGIFS of 1.0 or less (as determined in section 5.1.6.3 of AHRI 210/240–202X).

5. Test Conditions

5.1 Test Conditions for Certifying Compliance With Standards

The following conditions specified in AHRI 210/240–202X apply when testing to certify to the SEER2 and HSPF2 energy conservation standards in § 430.32(c).

For cooling mode, use the rating conditions specified in table 8 of AHRI 210/240–202X and the fractional cooling bin hours in table 15 of AHRI 210/240–202X to determine SEER2, and EER2 for models subject to regional standards in terms of EER2.

For heat pump heating mode, use the rating conditions specified in table 8 of AHRI 210/240–202X and the fractional heating bin hours specified for Region IV in table 16 of AHRI 210/240–202X to determine the heating efficiency metric, HSPF2.

5.2 Optional Representations

Representations of EER2 made using the rating conditions specified in Table 8 of AHRI 210/240–202X are optional for models not subject to regional standards in terms of EER2. Representations of HSPF2 made using the rating conditions specified in table 8 of AHRI 210/240–202X and the fractional heating hours specified for Regions other than Region IV in Table 14 AHRI 210/240–202X are optional. Representations of COP_{peak} made using appendix K are optional.

■ 10. Appendix M2 to subpart B of part 430 is added to read as follows:

Appendix M2 to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Central Air Conditioners and Heat Pumps

Note: Prior to [*Date 180 days after publication of the final rule in the* ***Federal Register***], representations with respect to the energy use or efficiency of central air conditioners and heat pumps, including compliance certifications, must be based on testing conducted in accordance with:

(a) Appendix M1 to this subpart, in the 10 CFR parts 200 through 499 edition revised as of January 1, 2023; or

(b) Appendix M1 to this subpart.

Beginning [*Date 180 days after publication of the final rule in the* ***Federal Register***], and prior to the compliance date of amended standards for central air conditioners and heat pumps based on Seasonal Cooling and Off-mode Rating Efficiency (SCORE) and Seasonal Heating and Off-mode Rating Efficiency (SHORE), representations with respect to energy use or efficiency of central air conditioners and heat pumps, including compliance certifications, must be based on testing conducted in accordance with appendix M1 to this subpart.

Beginning on the compliance date of amended standards for central air conditioners and heat pumps based on SCORE and SHORE, representations with respect to energy use or efficiency of central air conditioners and heat pumps, including compliance certifications, must be based on testing conducted in accordance with this appendix.

Manufacturers may also certify compliance with any amended energy conservation standards for central air conditioners and heat pumps based on SCORE or SHORE prior to the applicable compliance date for those standards, and those compliance certifications must be based on testing in accordance with this appendix.

1. Incorporation by Reference

In § 430.3, DOE incorporated by reference the entire standard for AHRI 1600–202X, ANSI/ASHRAE 16–2016, ANSI/ASHRAE 37–2009, and ANSI/ASHRAE 116–2010. However, certain enumerated provisions of AHRI 1600–202X, ANSI/ASHRAE 16–2016, ANSI/ASHRAE 37–2009, and ANSI/ASHRAE 116–2010, as set forth in sections 1.1 through 1.4 of this appendix, are inapplicable. To the extent there is a conflict between the terms or provisions of a referenced industry standard and the CFR, the CFR provisions control.

1.1. AHRI 1600–202X

(a) Section 1 Purpose is inapplicable,
(b) Section 2 Scope is inapplicable,
(c) The following subsections of Section 3 Definitions are inapplicable: 3.1.15 (Double-duct system), 3.1.19 (Gross capacity), 3.1.47 (Oil Recovery Mode), 3.1.52 (Published Rating), 3.1.65 (Standard Filter), 3.1.80 (Unitary Air-conditioner), 3.1.81 (Unitary Heat Pump),
(d) Section 4 Classifications is inapplicable,
(e) The following subsections of Section 6 Rating Requirements are inapplicable: 6.1.8, 6.2, 6.3, 6.4 and 6.5
(f) Section 7 Minimum Data Requirements for Published Ratings is inapplicable,
(g) Section 8 Operating Requirements is inapplicable,
(h) Section 9 Marking and Nameplate Data is inapplicable,
(i) Section 10 Conformance Conditions is inapplicable,
(j) Appendix A References—Normative is inapplicable,
(k) Appendix B References—Informative is inapplicable,
(l) Appendix C Secondary Capacity Check Requirements—Normative is inapplicable,
(m) Appendix F Unit Configurations for Standard Efficiency Determination—Normative is inapplicable,
(n) Appendix H Verification Testing—Normative is inapplicable,
(o) Appendix I Controls Verification Procedure—Normative is inapplicable,
(p) Appendix J Determination of Cut in and Cut out temperatures—Normative is inapplicable, and
(q) Appendix M Outdoor Temperature Bin Hours—Informative is inapplicable.

1.2. ANSI/ASHRAE 37–2009

(a) Section 1—Purpose is inapplicable,
(b) Section 2—Scope is inapplicable, and
(c) Section 4—Classification is inapplicable.

1.3. ANSI/ASHRAE 16–2016

(a) Section 1—Purpose is inapplicable,
(b) Section 2—Scope is inapplicable, and
(c) Section 4—Classification is inapplicable.

1.4. 1.4. ANSI/ASHRAE 116–2010

(a) Section 1—Purpose is inapplicable,
(b) Section 2—Scope is inapplicable,
(c) Section 4—Classification is inapplicable,
(d) Section 7—Methods of Test is inapplicable,
(e) References is inapplicable,
(f) Appendix A—Example Bin Calculations is inapplicable, and
(g) Appendix B—Bibliography is inapplicable.

2. General

Determine the applicable energy efficiency metrics (SCORE, SHORE, and EER2) in accordance with the specified sections of AHRI 1600–202X and the applicable provisions of ANSI/ASHRAE 16–2016, ANSI/ASHRAE 37–2009, and ANSI/ASHRAE 116–2010. The A_{Full} (cooling mode) and $H_{1, Full}$ or $H_{1, Nom}$ (heating mode, if applicable) shall have a secondary capacity check completed. For all other tests in each mode, it is permissible to not use a secondary capacity check. Sections 3 and 4 of this appendix provide additional instructions for testing. In cases where there is a conflict, the language of this appendix takes highest precedence, followed, in order, by: AHRI 1600–202X, ANSI/ASHRAE 37–2009, ANSI/ASHRAE 16–2016, and ANSI/ASHRAE 116–2010. Any subsequent amendment to a referenced document by the standard-setting organization will not affect the test procedure in this appendix, unless and until the test procedure is amended by DOE. Material is incorporated as it exists on the date of the approval, and a notice of any change in the incorporation will be published in the **Federal Register**.

3. Outdoor Units With No Match (OUWNM)

3.1 Definition

An Outdoor Unit that is not distributed in commerce with any indoor units, that meets any of the following criteria:

(a) Is designed for use with a refrigerant that makes the unit banned for installation when paired with an Indoor Unit as a system, according to EPA regulations in 40 CFR chapter I, subchapter C,

(b) Is designed for use with a refrigerant that has a 95 °F midpoint saturation absolute pressure that is ±18 percent of the 95 °F saturation absolute pressure for R–22, or

(c) Is shipped without a specified refrigerant from the point of manufacture or is shipped such that more than two pounds of refrigerant are required to meet the charge per section 5.1.8 of AHRI 1600–202X. This shall not apply if either:

(1) The factory charge is equal to or greater than 70% of the outdoor unit internal volume times the liquid density of refrigerant at 95 °F or,

(2) An A2L refrigerant is approved for use and listed in the certification report.

3.2 Testing

An OUWNM shall be tested with an indoor coil having nominal tube diameter of 0.375 in and an NGIFS of 1.0 or less (as determined in section 5.1.6.3 of AHRI 1600–202X).

4. Test Conditions

4.1 Test Conditions for Certifying Compliance With Standards

The following conditions specified in AHRI 1600–202X apply when testing to certify to the SCORE and SHORE energy conservation standards, in § 431.97.

For cooling mode, use the rating conditions specified in table 8 of AHRI 1600–202X and

the 'U.S. National Average' cooling conditioning hours and shoulder season hours in Table 15 of AHRI 1600–202X, to determine SCORE, and EER2 for models subject to regional standards in terms of EER2.

For heat pump heating mode, use the rating conditions specified in Table 8 of AHRI 1600–202X and the 'U.S. National Average' heating conditioning hours and shoulder season hours specified in Table 18 of AHRI 1600–202X to determine the heating efficiency metric, SHORE.

4.2 Optional Representations

Representations of EER2 made using the rating conditions specified in Table 8 of AHRI 1600–202X are optional for models not subject to regional standards in terms of EER2. Representations of SHORE made using the rating conditions specified in Table 8 of AHRI 1600–202X and the 'Cold Climate Average' heating conditioning hours and shoulder season hours in Table 18 of AHRI 1600–202X are optional. Representations of COP_{peak} made using appendix K are optional.

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Part IV

Department of the Interior

Fish and Wildlife Service

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 402

Endangered and Threatened Wildlife and Plants; Regulations for Interagency Cooperation; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 402

[Docket No. FWS–HQ–ES–2021–0104; FXES1114090FEDR–245–FF09E300000; Docket No. NMFS–240325–0087]

RIN 1018–BF96; 0648–BK48

Endangered and Threatened Wildlife and Plants; Regulations for Interagency Cooperation

AGENCY: U.S. Fish and Wildlife Service (FWS), Interior; National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: FWS and NMFS (collectively referred to as the ''Services'' or ''we'') finalize revisions to portions of our regulations that implement section 7 of the Endangered Species Act of 1973, as amended (''Act''). The revisions to the regulations clarify, interpret, and implement portions of the Act concerning the interagency cooperation procedures.

DATES: This final rule is effective May 6, 2024.

ADDRESSES: Public comments and materials received, as well as supporting documentation used in the preparation of this final rule, are available online at *https://www.regulations.gov* at Docket No. FWS–HQ–ES–2021–0104.

FOR FURTHER INFORMATION CONTACT: Craig Aubrey, Ecological Services, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, Falls Church, VA 22041–3803; telephone 703/358–2442; or Tanya Dobrzynski, Chief, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910, telephone 301/427–8400. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Background

The Secretaries of the Interior and Commerce (the ''Secretaries'') share responsibilities for implementing most of the provisions of the Endangered Species Act, as amended (hereafter referred to as ''ESA'' or ''the Act;'' 16 U.S.C. 1531 *et seq.*), and authority to administer the Act has been delegated by the respective Secretaries to the Director of FWS and the Assistant Administrator for NMFS. Together, the Services have promulgated procedural regulations governing interagency cooperation under section 7 of the Act, which requires Federal agencies, in consultation with and with the assistance of the Secretaries of the Interior and Commerce, to ensure that any action authorized, funded, or carried out by such agencies is not likely to jeopardize the continued existence of endangered or threatened species or result in the destruction or adverse modification of critical habitat of such species. These joint regulations, which are codified in the Code of Federal Regulations at 50 CFR part 402, were most recently revised in 2019 (84 FR 44976, August 27, 2019; hereafter referred to as ''the 2019 rule''). Those revised regulations became effective October 28, 2019 (84 FR 50333, September 25, 2019).

Executive Order 13990 (hereafter, ''E.O. 13990''), which was entitled ''Protecting Public Health and the Environment and Restoring Science To Tackle the Climate Crisis,'' was issued January 20, 2021, and directed all departments and agencies to immediately review agency actions taken between January 20, 2017, and January 20, 2021, and, as appropriate and consistent with applicable law, consider suspending, revising, or rescinding agency actions that conflict with important national objectives, including promoting and protecting our public health and the environment, and to immediately commence work to confront the climate crisis. A ''Fact Sheet'' that accompanied E.O. 13990 identified a non-exhaustive list of particular regulations requiring such a review and included the 2019 rule (see *www.whitehouse.gov/briefing-room/statementsreleases/2021/01/20/fact-sheet-list-of-agency-actions-for-review/*). In response to E.O. 13990 and in light of litigation over the 2019 rule, the Services proposed revisions to portions of the ESA implementing regulations at 50 CFR part 402.

On June 22, 2023, we published in the **Federal Register** (88 FR 40753) a proposed rule to amend portions of our regulations that implement section 7 of the Act. We accepted public comments on the June 22, 2023, proposed rule for 60 days, ending August 21, 2023. The proposed rule included clarifying the definitions of ''effects of the action,'' ''environmental baseline,'' and ''reasonable and prudent measures''; removing § 402.17, ''Other provisions,'' which had been promulgated with the intent of clarifying several aspects of the process of determining whether an activity or consequence is reasonably certain to occur; clarifying the responsibilities of the Federal agency and the Services regarding the requirement to reinitiate consultation; and revising the regulations at 50 CFR 402.02 and 402.14 regarding the scope of reasonable and prudent measures (RPMs) in an incidental take statement (ITS). The proposed rule also sought comment on all aspects of the 2019 rule, including whether any of those provisions should be rescinded in their entirety (restoring the prior regulatory provision) or revised in a different way. The Services also conducted outreach to Federal and State agencies, industries regularly involved in section 7(a)(2) consultation, Tribes, nongovernmental organizations, and other interested parties and invited their comment on the proposal.

Following consideration of all public comments received in response to our proposed rule, we are proceeding to finalize revisions to our implementing regulations at 50 CFR part 402 as proposed, with no changes. The basis and purpose for this final rule are reflected in our explanation in the June 2023 proposed rule, the responses to comments below, as well as the 2019 final rule for those aspects of the 2019 final rule we are not changing here. These revisions will further improve and clarify interagency consultation. With the exception of the revisions at 50 CFR 402.02 and 402.14 regarding the RPMs in an incidental take statement (ITS), the revisions do not make any changes to existing practice of the Services in implementing section 7(a)(2) of the Act.

In the event any provision is invalidated or held to be impermissible as a result of a legal challenge, the ''remainder of the regulations could function sensibly without the stricken provision.'' *Belmont Mun. Light Dep't* v. *FERC,* 38 F.4th 173, 187 (D.C. Cir. 2022) (quoting *MD/DC/DE Broad. Ass'n* v. *FCC,* 236 F.3d 13, 22 (D.C. Cir. 2001)). Because each of the revisions stands on its own, the Services view each revision as operating independently from the other revisions. Should a reviewing court invalidate any particular revision(s) of this rulemaking, the

remaining portions would still allow the Services to issue biological opinions and incidental take statements that comprehensively evaluate the effects of federal actions on listed species and critical habitat and adequately address the impacts of incidental take that are reasonably certain to occur. Specifically, these distinct provisions include: (1) revisions to the definition of ''environmental baseline,'' (2) removal of section § 402.17 and conforming revisions to the definition of ''effects of the action,'' (3) revisions to § 402.16, and (4) revisions to the regulatory provisions regarding the scope of reasonable and prudent measures in incidental take statements (§§ 402.02 and 402.14(i)). To illustrate this with one possible example, in the event that a reviewing court were to find the revision adopted in 2019 that described expedited consultations at § 402.14(l) is invalid, that finding would not affect the current revisions to the provisions for reinitiation of consultation at Section § 402.16.

The revisions to the regulations in this final rule are prospective; they are not intended to require that any previous consultations under section 7(a)(2) of the Act be reevaluated at the time this final rule becomes effective (see **DATES**, above).

This rule is one of three rules publishing in today's **Federal Register** that make changes to the regulations that implement the ESA. Two of these final rules, including this one, are joint between the Services, and one final rule is specific to FWS.

Summary of Comments and Responses

In our June 22, 2023, proposed rule (88 FR 40753), we requested public comments by August 21, 2023. We received more than 140,000 comments by that date from individual members of the public, States, Tribes, industry organizations, legal foundations and firms, and environmental organizations. We received several requests for extensions of the public comment period. However, we elected not to extend the public comment period because we found the 60-day comment period provided sufficient time for a thorough review of the proposed revisions. The majority of the proposed revisions are to portions of the regulations that were previously revised in 2019, and we jointly announced in a public press release and on a Service website our intention to revise these regulations in June of 2021. The number of comments received indicated that members of the public were aware of the proposed rule and had adequate time to review it. In addition, we provided six informational sessions for a wide variety of audiences. Over 500 attendees participated in these sessions, and we addressed questions from the participants during each session. Finally, on our website, we provided additional information about the proposed regulations, such as frequently asked questions and a prerecorded presentation on the proposed revisions.

Most of the comments we received were non-substantive, expressing either general support for, or opposition to, the proposed rule with no supporting information or analysis. Other comments expressed opinions beyond the scope of this rulemaking. We do not, however, respond to comments that are beyond the scope of this rulemaking action or that were not related to the 2019 rule. The vast majority of the comments received were nearly identical statements from individuals indicating their general support for the proposed revisions to the 2019 rule and concern for not including more revisions to the 2019 rule, but not containing substantive content. We also received approximately 95 letters with detailed substantive comments with specific rationales for support of or opposition to specific portions of the proposed rule.

Before addressing each of the comments, we reiterate the Services' intention to provide additional guidance in an updated ESA Section 7 Consultation Handbook (Consultation Handbook) that we anticipate making available for public comment after the publication of this final rule. Related to topics addressed in this final rule, the additional guidance will address application of the definition of ''effects of the action'' and ''environmental baseline,'' examples for defining when an activity is reasonably certain to occur and guidance on application of the two-part causation test, additional information on consulting programmatically, guidance on implementation of section 7(a)(1) of the Act, and implementation of the expanded scope of RPMs.

Recognizing that the revisions to the regulatory provisions expanding the scope of RPMs represent a change to the Services' practice, we would also like to highlight some of the key aspects of that amendment, which are discussed in more detail in the response to comments below. First, the Services find that the revision allowing for the use of offsets as RPMs will more fully effectuate the conservation goals of the ESA by addressing impacts of incidental take that may not have been sufficiently minimized through measures confined to avoiding or reducing incidental take levels. In that regard, our prior approach, which restricted RPMs to measures that avoid or reduce incidental take, has led to the continued deterioration of the condition of listed species and their critical habitat through the accumulation of impacts from incidental take over time. Further, those impacts from incidental take may have been more adequately addressed through offsetting measures.

Second, as explained in our response to comments below, the respective revisions to § 402.02 and § 402.14(i), which recognize the use of offsets as RPMs, are supported by the plain language of the ESA. The relevant language at ESA section 7(b)(4)(C)(ii) plainly states that RPMs are to include measures that minimize the ''impacts'' of incidental take, not just incidental take itself. Like measures that avoid or reduce incidental take, offsetting measures also ''minimize'' the impacts of incidental take on the species. The legislative history of the 1982 amendments of the ESA also confirms that Congress did not intend to preclude the Services from specifying offsets as RPMs that minimize the impacts of incidental take. Lastly, the Services do not expect offsetting measures that occur outside the action area to violate the ''minor change rule.'' In most instances, offsetting measures operate as additional measures to minimize impacts of incidental take that would not prevent the action subject to consultation from proceeding essentially as proposed. Accordingly, text was added at 50 CFR 402.14(i)(2) to expressly recognize that offsets may occur within or outside the action area, consistent with the ''minor change rule'' (*i.e.,* the requirement that RPMs specify only minor changes that do not alter the basic design, location, duration, or timing of the action).

In addition, the Services would like to address a particular issue at the outset of this portion of the preamble. Several commenters asserted that a recent decision from the D.C. Circuit Court of Appeals, *Maine Lobstermen's Association* v. *NMFS,* 70 F.4th 582 (D.C. Cir. 2023) (''*MLA*''), weighs against the Services removing § 402.17 from the section 7 regulations, especially the ''clear and substantial information'' standard that applies in determining if a consequence is reasonably certain to occur. We explain here our understanding of the decision and why it does not undermine our regulatory revision to remove § 402.17. Because the subject consultation in the *MLA* litigation required NMFS to grapple with scientific uncertainties, we also offer additional explanation of how the

Services address such uncertainties, in general, consistent with the holding in *MLA* and section 7(a)(2) of the Act. We respond to some of the more specific comments in the responses section below.

In *MLA,* lobster fishermen challenged a NMFS no-jeopardy biological opinion that analyzed the effects of authorizing the Federal lobster and Jonah crab fisheries in the Northeast on the highly endangered North Atlantic right whale. In developing the biological opinion, NMFS faced uncertainties in determining the anticipated level of right whale entanglements and any subsequent deaths the fishery was anticipated to cause over the next 50 years. The D.C. Circuit Court of Appeals found that NMFS impermissibly resolved these uncertainties by asserting the legislative history of the ESA required NMFS to apply worst case scenarios. See 70 F.4th at 597 (''When answering public comments the Service blamed the Congress, insisting that . . . the legislative history required it to deal in worst-case scenarios because 'we need to give the benefit of the doubt to the species.' ''). The *MLA* court held that legislative history cannot ''compel a presumption in favor of the species not required by the statute'' and that, under the ESA, the Services facing scientific uncertainty may not simply resort to ''worst-case scenarios or pessimistic assumptions,'' but must instead ''strive to resolve or characterize the uncertainty through accepted scientific techniques.'' *Id.* at 586, 598, 600.

That decision does not address the Services' discretion to resolve ambiguities in the best available scientific data generally, or the Services' decision to remove § 402.17 from the section 7 regulations. First, the court invalidated only the particular way in which NMFS resolved uncertainties in *MLA*—namely that the agency, in the court's view, made a legal determination that it had to give the benefit of the doubt to an endangered species, rather than making a scientific judgment based on the best available scientific data. The court stated, for example, that agencies may not ''jump to a substantive presumption [in favor of the endangered species] that distorts the analysis of effects and creates false positives.'' *MLA,* 70 F.4th at 600. But the court also made clear that when agencies make ''a scientifically defensible decision'' by, for instance, ''striv[ing] to resolve or characterize the uncertainty through accepted scientific techniques,'' their ''predictions will be entitled to deference.'' *Id.* The court further anticipated that NMFS ''will be able to make'' such scientifically defensible decisions ''[i]n most realistic cases'' and thereby avoid the specific issues the court found problematic in *MLA. Id.* The Services historically have resolved ambiguities or uncertainties in the data based on such ''accepted scientific techniques.'' As a result, the Services anticipate that the *MLA* decision will have limited implications for the Services' overall implementation of section 7(a)(2).

Second, *MLA* does not constrain the Services' decision to remove § 402.17, contrary to some commenters' assertions. As discussed more fully below, the Services are removing the ''clear and substantial information'' requirement because it could be read as inappropriately restricting the scope of ''the best available scientific and commercial data'' by demanding a degree of certitude and quantification. The best available data are not always free of ambiguities and thus ''clear,'' nor are they invariably quantifiable or ''substantial'' in quantity. As the Services explained in the 2019 section 7 final rule: The best scientific and commercial data available is not limited to peer-reviewed, empirical, or quantitative data but may include the knowledge and expertise of Service staff, Federal action agency staff, applicants, and other experts, as appropriate, applied to the questions posed by the section 7(a)(2) analysis when information specific to an action's consequences or specific to species response or extinction risk is unavailable. Methods such as conceptual or quantitative models informed by the best available information and appropriate assumptions may be required to bridge information gaps in order to render the Services' opinion regarding the likelihood of jeopardy or adverse modification. Expert elicitation and structured decision-making approaches are other examples of approaches that may also be appropriate to address information gaps. (84 FR 45000)

MLA does not require a different view. In interpreting section 7(a) of the ESA, the court held that agencies must use ''the best available scientific data, not the most pessimistic.'' *MLA,* 70 F.4th at 599. The court did not hold that, within the best available scientific data, the statute permits reliance only on clear data that lack uncertainties or a substantial amount of such data. And while the court made a passing reference to § 402.17, it did so to support the proposition that, even under the Services' own ''interpretive rules,'' NMFS's approach in that case fell short because, in the court's view, it lacked a clear and substantial basis for predicting reasonably certain effects. The court did not indicate the *statute* demands ''clear and substantial information.''

That understanding is consistent with the statutory text, which provides that each federal agency shall ''*insure* that any action authorized, funded, or carried out by such agency . . . is *not* likely to jeopardize the continued existence of any endangered species or threatened species.'' 16 U.S.C. 1536(a)(2) (emphases added). As the Supreme Court has explained, ''insure'' in section 7(a)(2) means ''[t]o make certain, to secure, to guarantee.'' *National Association of Home Builders* v. *Defenders of Wildlife,* 551 U.S. 644, 667 (2008) (quotation marks omitted). Thus, agencies do not determine the effects of an action using ''the best scientific and commercial data available'' in a vacuum. Rather, the ESA envisions that agencies would make any such scientific judgments in service of their overarching responsibility to ''make certain'' their actions are ''not likely'' to jeopardize protected species. Accordingly, a regulation that impairs agencies' ability to carry out that duty by requiring them to disregard any reasonably certain effects that have ambiguities in the underlying information or that may be based on less than substantial information could be inconsistent with the statute.

We note that even with the removal of § 402.17, the two-part causation test (*i.e.,* the ''but for'' and ''reasonably certain to occur'' standards) for determining whether a particular activity or consequence falls under the definition of ''effects of the action'' remains in place. As the Services explained in the 2019 rule, the ''reasonably certain to occur'' standard adds an element of foreseeability and a limitation to our causation standard for determining ''effects of the action.'' 84 FR at 44991. That standard prevents the Services from engaging in speculative analyses, though it does not require a guarantee that an effect will occur. *See* 51 FR 19926 at 19932–19933; June 3, 1986 (1986 section 7 regulations final rule); 80 FR 26832 at 26837; May 11, 2015 (incidental take statement final rule); 83 FR 35178 at 35183; July 25, 2018 (2018 proposed rule to update section 7 regulations). These safeguards ensure that when faced with scientific uncertainties, the Services will not automatically rely on ''worst-case scenarios.'' *See* 84 FR 44967 at 45000; August 27, 2019. Instead, consistent with the statute and our regulations, the Services will continue to evaluate the best available evidence to arrive at principled scientific determinations in rendering our opinion under section 7

of the Act. Similarly, in rendering our opinion and resolving uncertainties, we will continue to be mindful of the fundamental duty—required by the text of section 7(a)(2)—to ''insure'' the agency action is not likely to jeopardize species protected under the Act.

Below, we summarize and respond to substantive and other relevant comments we received during the public comment period; we combined similar comments where appropriate.

Section 402.02—Definitions

Definition of ''Effects of the Action''

As proposed, we are revising the definition of ''effects of the action'' by adding ''but that are not part of the action'' to the end of the first sentence and removing the parenthetical reference to § 402.17. The first sentence now reads: Effects of the action are all consequences to listed species or critical habitat that are caused by the proposed action, including the consequences of other activities that are caused by the proposed action but that are not part of the action. The Services received a wide variety of comments on our proposed revisions to the definition of ''effects of the action.'' These comments ranged from support of the proposed revisions, requests to revert to the pre-2019 definition, and recommendations for modifications to the proposed definition, largely to incorporate portions of § 402.17 in the ''effects of the action'' definition if that section is removed as had been proposed. Commenters in support of the revisions to the 2019 definition generally agreed with the reasoning of the Services but many requested additional guidance on the application of the definition. The Services intend to provide additional guidance in an updated Consultation Handbook, which we anticipate publishing in the **Federal Register** for public comment after issuance of this final rule.

Commenters who requested the Services return to the pre-2019 definition of ''effects of the action'' generally pointed to the removal of the terms ''direct,'' ''indirect,'' interrelated,'' and ''interdependent'' and the use of the terms ''consequences'' and ''other activities,'' as well as the two-part causation test as being a change in practice that narrows the scope of the ''effects of the action.'' The Services respectfully decline to return to the pre-2019 definition of ''effects of the action.'' We reassert our position that the retained changes in the 2019 rule and the revisions adopted from the 2023 proposed rule maintain the pre-2019 scope of the effects analysis. These changes provide further clarity in the application of the longstanding practice of determining the full range of effects of a proposed action under consultation, including those that result from other activities that would not occur but for the proposed action. Under the pre-2019 definition, there was undue focus on categorizing the specific type of effect analyzed as part of the ''effects of the action'' (*i.e.,* assigning effects to the categories of direct, indirect, interrelated, or interdependent). The changes promulgated in 2019 to the definition avoided that exercise of categorizing the effects, but all these effects are, nevertheless, still analyzed as part of the ''effects of the action.'' Many commenters requested the Services retain the reference to § 402.17 in the ''effects of the action'' definition and the content of § 402.17. The comments related to § 402.17 and the ''effects of the action'' definition centered on the two-part causation test, particularly the framework provided for determining whether an activity or consequence is reasonably certain to occur. Those comments that focused on § 402.17 are addressed below in the preamble to this final rule.

Comment 1: One commenter recommended adding the word ''likely'' to the definition of ''effects of the action'' to assist in distinguishing that consequences of the action must be likely to occur in order to result in effects.

Response: The current definition and the ''but for'' and ''reasonably certain to occur'' causation provide a clear test of what constitutes an effect of the action, including for other activities caused by the action. Adding the term ''likely'' would add ambiguity rather than clarifying the test for an effect of the action. The Services respectfully decline this requested change to the definition of ''effects of the action.''

Comment 2: Several commenters proposed incorporating the statutory requirement to use the best available scientific and commercial data into the ''effects of the action'' definition to support the two-part causation test.

Response: The last sentence of section 7(a)(2) of the Act requires both the Federal action agencies and the Services to use ''the best scientific and commercial data available.'' This requirement applies to all aspects of the Services' application of section 7(a)(2) consultation, including determining what activities or consequences are considered reasonably certain to occur when analyzing the ''effects of the action'' and any ''cumulative effects.'' Therefore, we respectfully decline the suggestion to add ''using the best scientific and commercial data available'' to the ''effects of the action'' definition because using the best scientific and commercial data available is already an explicit requirement of the Act for agencies and incorporated into our formulation of the biological opinion under the regulations. See 16 U.S.C. 1536(a)(2), 50 CFR 402.14(g)(8).

Comment 3: Commenters recommended modifications to the definition of ''effects of the action'' to distinguish ''activities'' from the proposed action in order to apply the two-part causation test to both ''activities'' and ''consequences.''

Response: The modification of the definition in the 2023 proposed rule to add ''but that are not part of the action'' addresses this recommendation so the Services did not further modify the ''effects of the action'' definition. The reference to ''activities'' in the first sentence of the 2019 ''effects of the action'' definition and in the revised version of the definition in this final rule is to those activities that are caused by, but are not part of, the proposed action. Under the pre-2019 definition, as described in the 2018 preamble for the proposed rule to the 2019 rule, the intent in changing the definition to ''other activities'' that would have been considered ''indirect effects'' or ''interrelated'' or ''interdependent'' actions was for consultations to focus on identifying the full range of the consequences rather than categorizing them (84 FR 44976–44977, August 27, 2019; 83 FR 35178 at 35183, July 25, 2018). The two-part causation test is used to determine when a consequence of these other activities is caused by the proposed action because the other activities (and the consequences of them) would not occur ''but for'' the proposed action and are ''reasonably certain to occur.''

Comment 4: Several commenters suggested returning to the 1986 ''effects of the action'' definition to use the terms ''direct,'' ''indirect,'' ''interrelated,'' and ''interdependent.'' They believe the 2019 definition narrows the scope of ''effects of the action'' and argue that collapsing direct and indirect effects into a single ''consequences'' requirement changes past practice because indirect effects did not require ''but for'' causation prior to 2019. Commenters noted that the 1998 Consultation Handbook required ''but for'' only in analyzing ''take'' resulting from the action, as well as interrelated and interdependent actions.

Response: The 1986 definition of ''indirect effects'' referred to effects that are ''caused by'' the proposed action whereas the Services' 1998 Consultation

Handbook includes the phrase ''caused by or results from,'' both of which require an assessment of a causal connection between an action and an effect. The ''but for'' causation test in the 2019 revised definition of ''effects of the action'' and as modified in this final rule is similar to ''caused by'' or ''caused by or results from'' in that both tests speak to a connection between the proposed action and the consequent results of that action, whether they be (1) physical, chemical, or biotic consequences to the environment, the species or critical habitat, or (2) activities that would not occur but for the proposed action. Both tests require a determination of factual causation, and since 2019 we have not observed a change in the Services' practice in applying ''but for'' causation to consequences once termed ''indirect effects'' compared to the regulatory term ''caused by.'' As we noted in the preamble of the 2018 proposed rule, ''[i]t has long been our practice that identification of direct and indirect effects as well as interrelated and interdependent actions is governed by the 'but for' standard of causation.'' Similarly, as defined in § 402.02, ''incidental take refers to takings that *result from* . . . an otherwise lawful activity.'' 50 CFR 402.02 (emphasis added). Moreover, our 1998 Consultation Handbook states: ''In determining whether the proposed action is reasonably likely to be the direct or indirect cause of incidental take, the Services use the simple causation principle: *i.e.,* 'but for' the implementation of the proposed action. . . .'' (1998 Consultation Handbook, page 4–47). For these reasons, the Services continue to maintain that the ''but for'' test reflects the Services' long-standing practice and has not changed the scope of our analyses. Therefore, we decline the commenters' request.

Comment 5: Commenters recommended that consideration of effects of ongoing agency actions not be moved to the ''environmental baseline.'' They argued that, if ongoing agency actions are moved to the ''environmental baseline,'' it will be difficult for the Services to determine whether a species already exists in a state of baseline jeopardy because of these previously authorized ongoing Federal actions.

Response: The concept of ''baseline jeopardy'' originates from cases like *Nat'l Wildlife Fed.* v. *NMFS,* 524 F.3d 917, 930 (9th Cir. 2008) (''[l]ikewise, even where baseline conditions already jeopardize a species, an agency may not take action that deepens the jeopardy by causing additional harm''). As we noted in our responses to comments in the 2019 rule and re-affirm here, the Services' position on ''baseline jeopardy'' remains that the statute and regulations do not contain any provisions under which a species should be found to be already (pre-action) in an existing status of ''baseline jeopardy,'' such that any additional adverse impacts must be found automatically to meet the regulatory standards for ''jeopardize the continued existence of'' or ''destruction or adverse modification.'' See 84 FR 44976 at 44987; August 27, 2019. Please see the responses to comments on the definition of ''environmental baseline'' below for more details.

Comment 6: Commenters noted that, while the 2019 definition may reflect the Services' longstanding practice, codifying the two-pronged test affects agencies' ability to fulfill their duties under section 7. Many commenters reiterated concerns raised during rulemaking on the 2019 rule that moving ongoing actions and their effects from the ''effects of the action'' to the ''environmental baseline'' undermines the Services' ability to conduct a thorough jeopardy analysis. Commenters argue that moving ongoing activities to the ''environmental baseline'' will exclude them from the jeopardy analysis.

Response: The Services respectfully disagree with the comments that use of the two-part causation test affects the ability of agencies to fulfill their section 7(a)(2) responsibilities. As we stated in 2019 and in the preamble to the 2023 proposed rule, the use of the two-part causation test has been part of our practice since the 1986 final rule on interagency cooperation (51 FR 19926 at 19933; June 3, 1986) (the Services did not define ''effects of the action'' in the original 1978 section 7 regulations (43 FR 870; January 4, 1978)). Consultation under the Act is conducted on the effects of the entire proposed action (all consequences caused by the proposed action). To further clarify, proposed actions for ongoing activities, even those that incrementally improve conditions may still have adverse effects (*i.e.,* are not wholly beneficial), and require formal consultation. The analysis of an action's effects is fact-based and consultation-specific. In terms of the jeopardy and destruction-or-adverse-modification analyses, the Services consider the effects of the action added to the ''environmental baseline'' and cumulative effects in light of the status of the species and critical habitat. Therefore, removing the ''environmental baseline'' definition from the definition of ''effects of the action'' does not affect either jeopardy or destruction-or-adverse-modification analyses, and the Services decline the suggestion to retain ''environmental baseline'' in the ''effects of the action'' definition. We provide additional discussion of how ''ongoing activities'' are considered for purposes of the ''environmental baseline'' in the ''environmental baseline'' section of this preamble below.

Comment 7: Other commenters asserted that the ''effects of the action'' definition is overly broad and will unnecessarily restrict future projects requiring section 7 consultation because of the need for the Services and Federal action agencies to analyze an array of effects that are unrelated or only tangentially related to the proposed action. Conversely, several commenters asserted the proposed changes to the definition specific to the two-part causation test raise the bar for any future review of the effects of a proposed action without supporting rationale as to why a higher bar is needed. These commenters argue that the ''but for'' and ''reasonably certain to occur'' requirements of the two-part causation test are too high given that ''may affect'' is the trigger for consultation.

Response: The revisions made in the 2019 rule and the further minor revisions in this final rule will not shift the scope of effects we consider under our revised definition of ''effects of the action.'' Therefore, as explained in the 2019 rule, our analyses will neither raise nor lower the bar for the scope of analysis of effects that has been in place since 1986. All the effects of the action considered since the 1986 revisions to the definition are still included in the scope of ''effects of the action,'' and no other effects or activities that are not caused by the proposed Federal action will be included. To the extent that commenters are asserting we should further restrict the definition of ''effects of the action'' to only those effects within the jurisdiction or control of the Federal agency, we decline this request for the same reasons discussed in 2019. *See* 84 FR 44991, August 27, 2019. The revisions to the definition and the changes made in 2019 did not change existing practice in determining the effects of the action, which includes what were referred to as direct, indirect, interrelated, and interdependent in the 1986 definition of ''effects of the action.'' The improvements to the definition in the 2019 rule and in this revision include the explicit establishment of the two-part test for effects, which codifies the Services' longstanding analysis in a clear standard in order to be more consistent

and transparent. The Services do not find that the 2019 definition or the revised definition in this rule narrows or broadens the scope of the effects that would be considered in a section 7(a)(2) consultation. Similar comments were made relating to § 402.17; please see our responses pertaining to comments on that section of the proposed rule below in this preamble.

Comment 8: One commenter argued that removing the definition of ''reasonably certain to occur'' while leaving in the concept that effects are not bound by time or space will create an unworkable burden on the consulting agency because an agency will not be able to evaluate all possible effects. Eliminating the definition of ''reasonably certain'' removes the two-tier system for identifying effects.

Response: The Services are retaining ''reasonably certain to occur'' in the revisions to the ''effects of the action'' definition as part of the two-part causation test. As discussed above, the revisions to the definition in this final rule will not shift the scope of effects we consider in section 7(a)(2) consultations. In addition, while we provided guidance on the factors to consider when determining whether other activities are ''reasonably certain to occur,'' the Services did not define the term and do not intend to define it because we are not setting limits on the types of activities that are reasonably certain to occur. We intend to provide further guidance in an updated Consultation Handbook. See also our response to comments related to § 402.17.

Comment 9: Several commenters recommended retaining § 402.17 and the reference to it in the ''effects of the action'' definition or incorporating the content of § 402.17 in the definition if the section is removed from the regulations. Commenters also recommended examples for defining when an activity is reasonably certain to occur and guidance for action agencies and the Services to ensure consistency in the application of the test. In addition, commenters suggested regulatory language that considers additional factors such as the proximity of the action in relation to the effect, geographical distribution of effects, timing of the effect in relation to sensitive periods of a species' life cycle, the nature and duration of the effect, and disturbance frequency as described in the 1998 Consultation Handbook discussion on the multi-factor tests to analyze the effects of a proposed action and related activities on species and critical habitat. Conversely, another commenter supported the removal of § 402.17 but encouraged the Services to work towards a stricter, quantifiable definition of ''reasonably certain to occur.''

Response: The Services support the recommendation to provide examples for defining when an activity is reasonably certain to occur and guidance on application of the two-part causation test. We believe this information is more appropriately addressed in an update to the Consultation Handbook rather than regulatory text. The Services update to the Consultation Handbook will incorporate changes to the regulations since the handbook was issued in 1998. For comments related to § 402.17, please see that section of the preamble below.

Comment 10: Some commenters indicated that the proposed changes to the ''effects of the action'' definition will cause greater uncertainty in terms of what to include in the effects of the action. Several also noted that the addition of the phrase ''but that are not part of the action'' to the definition is unclear and recommended that guidance be created by the Services to ensure the interpretation of ''not part of the action'' is consistent across offices and to clarify the scope or extent of activities outside the proposed action that will be analyzed. Conversely, other commenters believe the addition of ''but that are not part of the action'' is a helpful clarification and recommend further modification of the definition to clarify that the two-part causation test does not apply to the proposed action itself (as opposed to other activities caused by, but that are not part of, the proposed action).

Response: As discussed previously, the Services believe the minor revisions to the definition in this final rule will not shift the scope of effects considered in section 7(a)(2) consultations. The addition of ''but that are not part of the action'' to the definition is meant to maintain the scope of the analysis of the effects by clarifying that it includes other activities caused by the proposed action that are reasonably certain to occur. The Services respectfully decline the suggestion to further refine the definition to explicitly state that the two-part causation test does not apply to the proposed action itself but agree that guidance on the application of the two-part causation test is warranted and anticipate including this information in the updated Consultation Handbook.

Comment 11: One commenter argued that the ''but for'' causation standard casts a wider net than a ''proximate cause'' standard. The commenter maintains that a proximate cause is a cause that directly produces an event and without which the event would not have occurred. ''But for'' causation treats the effects of an action as a series of events and circumstances that can be traced to a particular action but without regard to whether either the agency action is responsible for or the agency has jurisdiction or authority to control those events and circumstances. The Services should revise the proposed ''effects of the action'' definition to eliminate the ''but for'' causation language and adopt a proximate cause standard.

Response: There is no Federal standard definition for ''proximate cause,'' a term that developed through judicial decisions. Proximate cause can differ if used for assigning liability in criminal action as compared to civil matters, neither of which is directly relevant in the section 7(a)(2) context of evaluating the anticipated effects of proposed Federal actions on listed species and critical habitat. We declined to include a proximate cause element in our definition of ''effects of the action'' in 2019 and do so again here. See 84 FR at 44990–44991, August 27, 2019. As discussed above, the ''but for'' causation standard is, in essence, a factual causation standard. As part of regular practice in conducting a complete analysis of the effects of proposed Federal actions, the Services' practice is to apply the concepts of ''but for'' causation and ''reasonably certain to occur'' when identifying the effects of the action. The changes to the ''effects of the action'' definition in our 2019 rule merely made them explicit. The Services' scope of the effects analysis did not change with the 2019 change to the ''effects of the action'' definition, and we do not anticipate a change in scope because of the minor changes to the ''effects of the action'' in this final rule.

Comment 12: Several commenters stated that the ''reasonably certain to occur'' limitation applied only to ''indirect effects'' and ''cumulative effects'' prior to the 2019 rule's ''effects of the action'' definition. They noted that this situation leads to exclusion of effects, but that uncertainty or data gaps should not be used to limit consideration of effects of a proposed agency action. They further argue that the reasonable certainty standard could conflict with the requirement to use the best available scientific and commercial data, particularly where there may be incomplete information or emerging science.

Response: We reaffirm what we stated in the 2019 rule, that the two-part effects test adopted at that time does not alter the scope of the Services' analysis.

The Services also agree that, in applying our two-part effects test, we must use the best available scientific and commercial data, which is expressly required by the statute and as part of our regulations at 50 CFR 402.14(g)(8). Consistent with considering the best available information, we will necessarily be required to exercise scientific judgment to resolve uncertainties and information gaps in applying our effects test. This process does not ignore effects but instead ensures that we adequately consider the range of effects caused by the proposed action. For further discussion relevant to this comment, please see the responses to comments regarding § 402.17.

Comment 13: Several commenters noted that the proposed change to the ''effects of the action'' definition will remove the framework for determining whether an activity or consequence is ''reasonably certain to occur'' that is critical for determining what to include in an agency's effects analysis, including when applying the standard to larger scales such as a program.

Response: The Services respectfully disagree with these comments; the definition and current practice adequately capture the ''reasonably certain to occur'' standard. As described in the 2019 rule, a section 7(a)(2) consultation performed at the level of a regional or national program is often referred to as a programmatic consultation, and often the proposed action falls into the category referred to as a framework programmatic action described in our 2015 rule revising incidental take statement regulations (80 FR 26832, May 11, 2015). In these instances, the ''but for'' and ''reasonably certain to occur'' parts of the test extend to the consequences that would be expected to occur under the program generally, but not to the specifics of actual projects that may receive future authorization under the program. Effects analyses at this more generalized level are necessary because the Federal agency often does not have specific information about the number, location, timing, frequency, precise methods, and intensity of the site-specific actions or activities for their program. We are able to provide an informed effects analysis at a more generalized level by analyzing the project design criteria, best management practices, standards and guidelines, and other provisions the program adopts to minimize the impact of future actions under the program.

Alternatively, some Federal agencies may be able to provide somewhat more specific information on, *e.g.,* the numbers, timing, and location of activities under their plan or program. In those instances, we may have sufficient information to address not only the generalized nature of the program's effects but also the specific anticipated consequences that are reasonably certain to occur from specific actions that will be subsequently authorized under the program. Additional guidance regarding application of the two-part causation test (''but for'' and ''reasonably certain to occur'') and programmatic consultation will be included in the updated Consultation Handbook. For more general discussion of the removal of the ''reasonably certain to occur'' framework provided by § 402.17, please see the responses to comments on that section in the preamble below.

Comment 14: Several commenters noted that the requirement that a ''reasonably certain to occur'' finding be based on ''clear and substantial information'' has created confusion and conflicts with the statutory requirement to use the ''best scientific and commercial data available'' and agreed with the removal of § 402.17 in its entirety. Another commenter supported retaining all of § 402.17, including the requirement to use ''clear and substantial information,'' noting that this language supports the requirement to use the ''best scientific and commercial data available.''

Response: The Services are removing § 402.17 via this final rule. The use of the terms ''clear and substantial information'' creates confusion with the statutory requirement to use the ''best scientific and commercial data available.'' We disagree with the comment that retaining the ''clear and substantial'' language in § 402.17 supports the required use of the ''best scientific and commercial data available.'' Please see the discussion of the term ''clear and substantial'' provided in response to comments on § 402.17.

Definition of ''Environmental Baseline''

As proposed, we are revising the third sentence of the definition of ''environmental baseline'' by replacing the term ''consequences'' with the word ''impacts,'' removing the term ''ongoing,'' and adding the term ''Federal'' in two locations. The third sentence now reads: The impacts to listed species or designated critical habitat from Federal agency activities or existing Federal agency facilities that are not within the agency's discretion to modify are part of the environmental baseline. The changes to the definition of ''environmental baseline'' in this rule are narrow and serve to clarify the intended application and scope of the final sentence that was added in 2019. The Services received a wide variety of comments on our proposed revisions to the definition of ''environmental baseline,'' most of which were focused on the original change in the 2019 rule. These comments ranged from support of the 2023 proposed revisions, requests to retain the original final sentence of the 2019 definition, and requests to remove the entire 2019 definition and revert to the definition as it stood prior to the 2019 rule. Commenters in support of the proposed revisions to the 2019 definition generally agreed with the reasoning of the Services and in some cases requested additional guidance on the application of the definition. The comments in opposition to the proposed revisions to the 2019 definition generally fell under two main themes of comments—both generally focused on the final sentence of the 2019 definition. One group focused specifically on the Services' revisions to the final sentence of the 2019 definition and whether and how the role of Federal agency discretion should be considered during a section 7 consultation. The second group focused on the proposed language changes to the final sentence, with most attention on opposition to the removal of the word ''ongoing.'' With regard to the request for additional guidance, the Services intend to provide additional guidance and examples in an updated Consultation Handbook.

Comment 1: Several commenters requested the Services revert entirely to the definition of ''environmental baseline'' as it stood prior to the 2019 regulations by either (1) pointing to other issues as described in other comments below or (2) attributing the entire definition to an earlier Presidential administration despite much of the text of the definition stemming from the pre-2019 regulations.

Response: The Services decline to return to the pre-2019 ''environmental baseline'' definition for several reasons. First, the 2019 definition retained much of the language of the pre-2019 definition, while also making the definition a stand-alone definition within the § 402.02 regulations. This regulatory change did not change the role of the ''environmental baseline'' in the section 7 consultation analysis, and the Services also reaffirmed in § 402.14(g)(4) that the analysis presented in the biological opinion must add the ''effects of the action'' to the ''environmental baseline'' and ''cumulative effects.'' This regulatory revision also removed a circular reference that occurred when the ''environmental baseline'' definition

was previously embedded within the ''effects of the action'' definition. By creating two separate definitions of ''effects of the action'' and ''environmental baseline,'' we are underscoring the separate nature of the analyses which are then to be combined into an aggregate assessment.

Second, by clarifying that those portions of a Federal activity or facility that are outside the control of the Federal agency to modify are included in the ''environmental baseline,'' the Services highlighted that the effects of discretionary activities or facilities contained in the proposed action would be evaluated within the context of (added to) the baseline and ''cumulative effects'' in order to determine whether those added effects were or were not ''likely to jeopardize'' a species. Third, in the 2019 ''environmental baseline'' definition, the Services clarified that the primary purpose of the ''environmental baseline'' is to present the condition of the listed species and critical habitat in the action area as impacted by the various factors of the ''environmental baseline.'' Prior interpretations of the pre-2019 definition could indicate that the baseline was simply a description of the impacts of those factors on the action area—missing the important connection to the condition of the species and critical habitat that may be further affected by the effects of a Federal action. With the 2019 rule, the Services highlighted two important elements: (1) That the purpose of the baseline was to assess the condition of the species and critical habitat and (2) that this condition assessment was taken into consideration prior to adding the consequences of the proposed action (which in some instances might be the future continued, discretionary operations of a facility such as a dam). These two elements provide the foundation to which the Services add the effects of the proposed action.

Comment 2: Some commenters reiterated their 2019 comments that the 2019 revised definition of ''environmental baseline'' hides or ignores the significant impacts of past and present activities and facilities, some of which may have played a significant role in the present status of the species and its critical habitat, asserting that the species is thus in ''baseline jeopardy.'' Further, commenters seem to imply that only large actions could then likely jeopardize listed species or destroy or adversely modify critical habitat.

Response: The Services disagree and have revised the definition's final sentence to clarify those aspects of a Federal action involving Federal facilities and activities that are in the ''environmental baseline'' and those that will be considered as ''effects of the action.'' As required by the regulations, the ''effects of the action'' will be added to the ''environmental baseline,'' thus the effects to a listed species or critical habitat already impacted by the ''environmental baseline'' will be considered in full light of the condition of that species and critical habitat. In addition to the overall status of the species, the relative health and viability of the species absent the proposed action in the action area is the starting point for the assessment and that condition informs the ability of the species to withstand further perturbations to its numbers, reproduction, and distribution. As we noted in our responses to comments in the 2019 rule and re-affirm here, the statute and regulations do not contain any provisions under which a species should be found to be already (pre-action) ''in baseline jeopardy,'' such that any additional adverse impacts must be found to meet the regulatory standards for ''jeopardize the continued existence of'' or ''destruction or adverse modification.'' As we further noted in 2019, and reaffirm here, the Services do not dispute that some listed species are more imperiled than others, and that for some very rare or very imperiled species, the amount of adverse effects to the species or its critical habitat that can occur without triggering a jeopardy or ''destruction or adverse modification'' determination may be small. See 84 FR 44976 at 44987, August 27, 2019.

Comment 3: A few commenters focused on the issue of Federal agency discretion and whether it was appropriate to further consider whether a Federal agency had discretion over some or all of its proposed action once consultation was initiated.

Response: Consultation under section 7(a)(2) is required when a discretionary Federal action may affect a listed species or designated critical habitat. As part of that process, it is important that the Federal action agency and the Services correctly identify the Federal action. Following this step, it is then also important to assess the ''effects of the action,'' which include the activities caused by (but are not part of) the proposed action and the effects of those activities. As the Services noted in the 2019 rule, and re-affirm here, the courts and the Services have concluded that, in general, the effects on listed species and critical habitat attributable to Federal agency activities and existing Federal agency facilities are part of the ''environmental baseline'' when the action agency has no discretion to modify them. For example, with respect to existing Federal facilities, such as a dam, courts have recognized that effects from the existence of the dam can properly be considered a past and present impact included in the ''environmental baseline'' when the Federal agency lacks discretion to modify the dam. *See, e.g., Friends of River* v. *NMFS,* 293 F. Supp. 3d 1151, 1166 (E.D. Cal. 2018). Under these lines of cases involving dams, when a Federal agency has authority for managing or operating a dam, but lacks discretion to remove or modify the physical structure of the dam, any impacts from the physical presence of the dam in the river are appropriately placed in the ''environmental baseline'' and are not considered an ''effect of the action'' under consultation. Thus, it is important to note that the above analytical process for determining the ''effects of the action'' does not include consideration of the discretion of the Federal action agency over the activities or facilities of another Federal agency or any other third party. To the extent that any effects are caused by the proposed Federal action, per the ''but for'' and ''reasonably certain to occur'' standards of the ''effects of the action'' definition, they would be considered as ''effects of the action'' in the consultation analyses. Those effects that are not caused by the Federal action would be included in the ''environmental baseline'' or ''cumulative effects'' as appropriate.

Comment 4: Several commenters advocated that the question of discretion should also apply to third party actions or the activities or facilities that are the subject of a Federal action, such as permitting or funding, with some commenters providing site-specific examples.

Response: As we noted above in this preamble and in the proposed rule, this determination is made on a case-by-case basis as determined by discussions between the Services and the appropriate Federal agency on the basis of the information and evidence available at the time. In most section 7 consultations, the question of discretion is not a factor and, indeed, several examples raised by commenters were on large-scale Federal activities such as water operations or land management, which make up a relatively small portion of ESA section 7 consultations. Many of the location-, activity-, or facility-specific concerns raised by some commenters are beyond the scope of this rule and best handled through site-specific consultations.

To answer some of the general questions or points of confusion, the Services note that the current revisions

are minor in scope to further clarify the intent of the final sentence added to the ''environmental baseline'' definition in 2019 and retained in this rule. These revisions do not modify current practice related to how past and present non-Federal actions are represented in the summary of impacts of the ''environmental baseline'' on the condition of listed species and critical habitat. In addition, the revisions do not alter current practice related to the analysis of the effects of a proposed discretionary Federal action that involves the authorization or funding of an action taken by a non-Federal entity such as a private landowner. The Services decline to speculate or generalize in a response to public comments as to the breadth of scope of agency discretion in all of these actions as these are case-specific determinations.

Comment 5: Some commenters requested additional discussion or guidance on how the determination of discretion would proceed. Another commenter argued that if discretion continues to be a factor when determining the ''environmental baseline'' the Services should retain the authority to make the determination on their own.

Response: As we noted in the proposed rule, we will work closely with the Federal action agency to understand the scope of their discretion in a particular case to inform those aspects of a Federal agency activity or facility that are a part of the ''environmental baseline.'' *See* 88 FR 40753 at 40756, June 22, 203. Typically, Federal discretion over an action or facility is defined within all the laws and regulations under which the action will be taken. Where questions regarding discretion arise during a consultation, the supporting record of the consultation should include the documentation upon which the separation between discretionary Federal agency action and those non-discretionary activities or facilities was made. While the Services ultimately determine the content and scope of the analyses in our biological opinions, generally we would defer to the Federal action agency's supported interpretation of their authorities for purposes of identifying what non-discretionary Federal facilities and activities are included in the ''environmental baseline.'' *See id.* As a general matter, the Services and an action agency can come to a specific understanding about the nature of an action agency's discretion and how to treat both effects of past and future actions stemming from the action agency's decisions.

Comment 6: One commenter objected to the definitions of ''environmental baseline'' and ''effects of the action'' because the commenter asserts that the effects of the action would include even those consequences of the Federal action that have occurred in the past and that the action agency and any proponent do not intend to change going forward and that the approach does not allow for adaptation due to climate change. The commenter also requested that the Services define the parameters of actions and effects for ongoing Federal project operations such that: (1) the proposed action should be the future discretionary actions related to the operation of the existing facilities in the existing environment; (2) the effects of the action should focus on the manner in which the current status of the species and existing condition of its habitat will be affected by the proposed future discretionary actions; and (3) the examination of effects of the discretionary proposed action does not include the baseline effects of or from the original construction of the facilities or the past operations and maintenance activities that have occurred.

Response: The Services decline to define the parameters of the ''environmental baseline'' and ''effects of the action'' as the commenter requests. The Services' definitions of ''effects of the action'' and ''environmental baseline'' are crafted to distinguish between those impacts that are properly considered as the ''environmental baseline'' and those consequences of a proposed discretionary Federal action that would be considered the ''effects of the action.'' Further, the baseline includes the original construction of facilities and past operations and maintenance that have occurred. However, the proposed future discretionary actions are all of the discretionary actions that will occur—even those ongoing discretionary actions for which no changes are envisioned. As we noted in the proposed rule, ''the Federal agency may propose to continue the operations of the dam's flow regime with no changes from past practices, or with only minor changes. Regardless of their ''ongoing'' nature, all the consequences of the proposed discretionary operations of the structure are ''effects of the action'' (88 FR 40753 at 40756, June 22, 2023). In other words, those future consequences of discretionary operations are properly considered ''effects of the action'' even if those similar operations that occurred in the past are included in the ''environmental baseline.'' A full assessment of the proposed Federal action will ultimately include the ''effects of the action'' added to the ''environmental baseline'' and any anticipated ''cumulative effects.'' Regarding the comment about consideration of climate change and the consideration of action effects and the ''environmental baseline,'' the Services note that climate change is considered as appropriate in all ESA section 7 consultations, including how past, present, and future conditions are impacted and the resulting ''effects of the action'' in context with those impacts.

Comment 7: One commenter requested information regarding future planned revisions to the ''environmental baseline'' definition.

Response: The Services note that the commenter may have misread the proposed rule. We do not anticipate further refining the definition of ''environmental baseline.''

Comment 8: Several commenters raised the issue of existing structures and how they would be considered under these regulations. Commenters inquired whether the 2019 regulations and the regulations in this rule allow for all existing structures to be included in the ''environmental baseline.'' Some commenters requested that the Services explicitly include that direction in the regulations. In other instances, commenters were concerned that the definition allows for past harms to the species and habitat to be ignored.

Response: The Services note that neither the 2019 definition of ''environmental baseline,'' nor the minor revisions adopted in this final rule, change current or past practice and thus do not treat existing structures differently than under the prior regulations. The final sentence of the definition in the 2019 rule was intended to clarify current practice and how the discretionary and non-discretionary portions of a Federal activity or facility are considered in the baseline and ''effects of the action.'' The Services decline to state that all existing structures are included in the ''environmental baseline''; existing structures may be included in the analysis of the ''effects of the action'' depending on the Federal action under consultation. Whether an existing structure is in the baseline is a case-specific determination that includes discretion, prior consultations, and temporal considerations.

Regarding concerns that the current definition allows for past impacts to be ignored by residing in the baseline, the Services restate that the 2019 baseline definition revision, which primarily made the definition a stand-alone

definition versus an embedded definition within the ''effects of the action,'' along with current regulations as amended, clarifies longstanding past and current practice in the treatment of those impacts that are a part of the ''environmental baseline.'' Importantly, by accounting for these past and present impacts in the baseline and then adding the effects of the proposed action to the ''environmental baseline,'' the Services do not ''let Federal agencies off the hook,'' as suggested by some commenters, but instead consider the consequences of a Federal action in the context of the past and present impacts to listed species and critical habitat in the action area.

The ESA section 7(a)(2) consultation process applies only when a Federal agency proposes to authorize, fund, or carry out a discretionary action that may affect a listed species or designated critical habitat. At that time, the effects of the proposed Federal action are analyzed and added to the impacts of the ''environmental baseline,'' which includes the past impacts raised by commenters. However, the section 7(a)(2) consultation process is not intended to ''right the wrongs of the past'' but to ensure that proposed Federal actions are ''not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat.'' As noted elsewhere, the health and viability of the species absent the proposed action is the starting point for the assessment and that condition informs the ability of the species to withstand further perturbations to its numbers, reproduction, or distribution. Thus, past impacts and the resulting condition of the listed species and critical habitat are crucial to the overall analysis in the section 7 consultation.

Comment 9: A few commenters requested deletion of the final sentence of the ''environmental baseline'' definition given the purported confusion it creates or perceived inappropriate narrowing or expansion of the scope of the definition. Others suggested different revisions from the Services' proposed minor amendments to the language.

Response: As noted previously, the sentence was added to distinguish those cases where an existing Federal facility or activity must be considered as part of the ''effects of the action'' versus past argued interpretations or confusion that all existing facilities and activities were de facto in the baseline. By evaluating the effects of discretionary actions against the backdrop of the ''environmental baseline'' and ''cumulative effects'' (future non-Federal activities that are reasonably certain to occur), the Services are able to assess whether the proposed action is ''likely to jeopardize a listed species'' or destroy or adversely modify critical habitat. This evaluation applies whether the proposed action is a novel action upon the landscape or a proposed action that includes another 10 years of the same types of consequences that have already led to species declines and habitat degradation.

The Services appreciate the suggested revisions to the final sentence of the ''environmental baseline'' definition, which some commenters offered in the event that their requests to delete the sentence were declined. However, the suggested revisions unintentionally resulted in the very concerns raised by the commenters, and in one case, would have inappropriately narrowed the scope of the ''environmental baseline.'' In that case, a commenter suggested not including in the ''environmental baseline'' past or completed Federal actions that have not undergone and completed section 7 consultation. The Services decline to accept this proposed revision, as it could have an unintended and significant negative effect on listed species and critical habitat. By removing from the ''environmental baseline'' the impacts of those past or completed Federal actions (some of which pre-date the ESA itself and have no discretionary Federal action to trigger consultation), the Services would be restricted to looking at an incomplete ''environmental baseline,'' and thus an incomplete jeopardy analysis.

Comment 10: The Services have revised the final sentence of the ''environmental baseline'' definition to replace the term ''consequences'' with ''impacts.'' We received comments both supporting and opposing this revision. While most understood the Services' intent to distinguish between those two terms, further explanation of the revision and the terms was requested.

Response: The Services appreciate the support for this revision to the final sentence of the ''environmental baseline'' definition. The Services understand the concern about the initial confusion with use of the term ''consequences'' to refer to those effects of a Federal action that were caused by the Federal action. The Services proposed to change the word ''consequences'' to ''impacts'' in the final sentence of the ''environmental baseline'' definition to address this confusion. More specifically, the ''environmental baseline'' and the ''effects of the action'' are two distinct assessments. Both are ultimately aggregated when the ''effects of the action'' are added to the ''environmental baseline.'' However, the Services sought to reduce confusion and overlap between the two definitions by retaining the use of ''consequences'' when discussing the effects of the proposed Federal action and using ''impacts'' when discussing the ''environmental baseline,'' even though we consider ''consequences,'' ''impacts,'' and ''effects'' to be equivalent terms.

Comment 11: One commenter requested that the ''environmental baseline'' not be limited to Federal projects, but instead include all projects that pre-date the ESA and all projects that have previously undergone ESA section 7 consultation. Further, the commenter requested clarification regarding the treatment of existing non-Federal projects (*e.g.,* residential or commercial piers and floats and private bulkheads), including the concept of ''useful life'' for both Federal and non-Federal actions.

Response: The Services affirm that the current definition of ''environmental baseline'' is not limited to just Federal projects, but we decline to state that ''all projects'' are automatically included in the ''environmental baseline.'' The definition includes (in relevant part,) ''the past and present impacts of all Federal, State, or private actions and other human activities in the action area, the anticipated impacts of all proposed Federal projects in the action area that have already undergone formal or early section 7 consultation, and the impact of State or private actions which are contemporaneous with the consultation process'' (50 CFR 402.02). The ''Federal projects'' in this excerpt refers to all actions proposed to be authorized, funded, or carried out by a Federal agency that have undergone consultation, which includes Federal permits for private or commercial actions. Because the definition of ''environmental baseline,'' including the minor revisions in this rule, does not change current practice, existing structures would be treated the same as they are under both current and prior practice (*i.e.,* before the 2019 regulation revisions). The Services decline to speak to the ''useful life'' of structures and how that issue would be treated nationwide as both are beyond the scope of this rule and would be addressed on a case-specific basis.

Comment 12: The Services received a wide range of comments on the proposed revision to the final sentence of ''environmental baseline'' to remove the word ''ongoing,'' and to insert the word ''Federal'' in two places. Some commenters opposed the revision

because they opposed application of the standard to only Federal activities or facilities. A few commenters requested that ''ongoing'' be retained because they assert that all activities or facilities that are ''ongoing'' should be included in the ''environmental baseline.'' Some commenters opposed the revision because the result would be either that more activities and facilities would be ''hidden'' in the ''environmental baseline'' and not in the ''effects of the action'' or fewer would be in the ''environmental baseline'' and included within the ''effects of the action.''

Response: Both the 2019 regulations and the regulations in this rule clarify existing practice related to the ''environmental baseline.'' While we cannot comment on the fact or site-specific circumstances that some commenters raise, every ESA section 7(a)(2) consultation is unique and based on what has been proposed by a Federal agency to authorize, fund, or carry out and the nature of the Federal agency's discretion and authority. Some of the examples raised may have included consultations that appropriately identified the Federal action and ''effects of the action'' based upon specific facts, applicable laws or other authorities, and prior consultation history. Thus, the conclusions in those examples do not necessarily apply in other instances, and it is incumbent on the Services and the Federal action agency to carefully describe and discuss what the Federal action may be in any particular case.

Several commenters were focused on the ''ongoing'' nature of an activity for determining whether that activity is evaluated in the environmental baseline. The Services proposed to remove the term ''ongoing'' and insert the term ''Federal'' because our experience implementing the 2019 rule echoes this same unintended focus on ''ongoing'' and not on the relevant portions of the sentence (*i.e.,* the scope of the Federal agency's discretion). As explained in our proposed rulemaking, we found that removal of the term ''ongoing'' from the relevant portion of the regulatory definition of ''environmental baseline'' would, instead, shift the focus to the appropriate factor for determining whether an activity is part of the ''environmental baseline''—whether or not the action agency has discretion to modify that activity. The Services decline to reinstate the term ''ongoing'' or remove the term ''Federal'' to avoid this improper focus in the future.

The Services also re-affirm that the pre-2019 definition, the 2019 definition, and the minor revisions in this rule maintain the same standards for the Federal, State, private, and other human activities that are considered in the ''environmental baseline'' and the scope of the effects of proposed Federal actions that will be analyzed as ''effects of the action.'' Existing non-Federal structures and activities occurring within an ''action area'' are a part of the ''environmental baseline,'' unless a Federal agency proposes to authorize, fund, or carry out an action related to the structure or activity. At that time, the non-Federal structure or activity may be subject to an ESA consultation if the proposed Federal action ''may affect'' listed species or designated critical habitat. Nothing in the revised ''environmental baseline'' definition changes this requirement of the statute. Despite the assertion of some commenters, if a Federal agency is proposing to authorize, fund, or carry out a repair or modification to a non-Federal structure, the consultation must evaluate the effects of the action, including all consequences to listed species or critical habitat caused by the proposed action.

Although commenters cite an example from the 1998 Consultation Handbook, that example fails to account for the wide variety of Federal actions that may occur related to an existing Federal facility, and thus one approach does not fit all situations. The Services again decline to universally state that all ''ongoing'' facilities or activities are in the ''environmental baseline.'' First, the term ''ongoing'' itself creates confusion when a longstanding operation that is within the discretionary authority of a Federal agency is being proposed for renewal. The prior operations are within the ''environmental baseline,'' but the future operations, which are part of the discretionary proposed action, are properly considered as effects of the action. In addition, the Services and Federal action agencies should work closely to examine and understand the consequences of a proposed Federal action. In some instances, the nature of the action may indeed result in a similar finding as the turbine example cited from the 1998 Consultation Handbook (See 1998 ESA Consultation Handbook, Chapter 4, Interrelated and Interdependent Actions p. 4–27). In other instances, the nature of the action may encompass more of the operations or even structure of the facility itself. It is beyond the scope of this rule to provide examples that cover all such possibilities. Case-specific circumstances must be considered and should be done in collaboration between the Services and the Federal action agency as discussed in the 2019 rule and the 2023 proposed rule.

The Services also clarify that the 2019 regulatory amendments, and the minor revisions in this final rule, do not remove existing structures and operations from the baseline as some commenters suggested. Similarly, the 2019 and 2023 revisions do not move most structures and operations to the proposed action if they are not either the proposed action itself or activities caused by the proposed action. The full definition of the ''environmental baseline'' includes those past impacts or Federal, State, and private actions in the action area. The final sentence is intended to address questions that have arisen regarding the consideration of the non-discretionary aspects of Federal facilities or activities. In general, Federal permitting and authorization of existing non-Federal facilities and activities is a discretionary action and requires section 7(a)(2) consultation if the proposed action may affect listed species or critical habitat. The past impacts of non-Federal facilities or non-Federal activities would be included in the ''environmental baseline'' whereas future consequences of the proposed Federal authorization action for that facility or activity would be the subject of the consultation and ''effects of the action'' analysis. In some instances, an effects analysis may need to assess the future and extended life of a structure, yet the past existence and impacts of the structure are included in the ''environmental baseline.''

The 2019 and current revisions to the ''environmental baseline'' definition do not prescribe particular assumptions that would be applied to all repair, maintenance, or modification activities proposed for authorization, funding, or implementation by a Federal agency. The consequences of such activities, including whether a proposed action extends the life of a structure or operation, would be reviewed per the standards of the ''effects of the action'' definition and may differ significantly from case to case. Further, what was or was not considered in prior consultations, if any, may also vary. The definition also does not prescribe how the effects of structures past their useful life would be analyzed as part of the ''environmental baseline.'' If those structures are not the subject of the consultation and are causing impacts to the condition of listed species and critical habitat in the action area, they would be included in the baseline, but it is beyond the scope of this rule to further describe or prescribe how that analysis would be done.

Comment 13: The Services received several comments specific to consultations on projects in the Salish Sea of Washington, an existing programmatic consultation, a NMFS 2018 internal guidance document, and the Puget Sound Nearshore Habitat Conservation Calculator.

Response: Generally, these comments are outside the scope of this rulemaking action, and given that the regulations do not alter current practice, the regulations are not expected to alter the consultations and tools raised by the commenters. Regarding the National Marine Fisheries Service, West Coast Region, Internal Guidance on Assessing the Effects of Structures in Endangered Species Act Section 7 Consultation (April 18, 2018), NMFS withdrew this guidance after issuance of the January 2022, Department of the Army (Civil Works) and the National Oceanic and Atmospheric Administration Memorandum. The 2022 Memorandum, which is based on existing legal requirements, is national in scope and clarifies potential differences between the U.S. Army Corps of Engineers Civil Works projects and Regulatory Program projects based on agency discretion. The 2022 memorandum is fully consistent with the Services' section 7 regulations, including the definitions of ''effects of the action'' and ''environmental baseline'' as revised in this final rule. The memorandum does not impose any new or additional requirements on action agencies, applicants, or NMFS, and does not alter the existing requirements relative to section 7 consultations. Commenters are correct that future Federal actions related to Federal or non-Federal facilities may trigger an ESA consultation on the proposed Federal action, but it is beyond the scope of this rule to speculate whether that consultation would require mitigation under existing programmatics or RPM offsetting measures, costly or otherwise.

Comment 14: One commenter questioned whether the modification to the final sentence of the ''environmental baseline'' definition forecloses the consideration of what used to be considered ''interrelated'' and ''interdependent'' actions as ''effects of the action.''

Response: The Services appreciate the commenter's perspective on the possible interpretation of the revised sentence. If the activities of other Federal agencies would be caused by the proposed Federal action that is subject to consultation, then they would properly be considered as ''effects of the action'' and those Federal agencies should be action agencies in the section 7(a)(2) consultation. Further, in situations where there are multiple Federal agencies taking actions (authorizing and funding, for example) on the same non-Federal action, an efficient consultation process could include all of these agencies (even if one is designated as the lead agency). Our interpretation and application of the ''environmental baseline'' and ''effects of the action'' definitions would not be a change in practice. In most cases, other Federal agency activities or facilities that are not caused by the proposed Federal action would be included within the ''environmental baseline'' (or subject to their own ESA consultation as needed). The Services decline to further revise the final sentence but note the commenter's concern for potential inclusion in further guidance.

Comment 15: One commenter was concerned that the addition of ''Federal'' in the final sentence of the ''environmental baseline'' definition restricted the ''effects of the action'' to only the consequences where the Federal action agency has the discretion to modify the activity or facility.

Response: Commenters misconstrue the effect of this revision. The Services are clarifying that the scope of application in the final sentence of ''environmental baseline'' is to Federal action agency (or agencies) activities and facilities. The inclusion of the word ''Federal'' does not alter the scope of the definition of ''effects of the action.'' As discussed in the ''effects of the action'' section above, if an activity or consequence meets the two-part test for an effect, then it is considered an ''effect of the action'' regardless of whether that activity or consequence is within the control of the Federal agency.

Comment 16: One commenter was concerned that the revision to the final sentence of ''environmental baseline'' implies that facilities such as irrigation, diking, and drainage infrastructure are not within the ''environmental baseline,'' and any future Federal permitting, even for maintenance and repair of existing infrastructure, would require costly mitigation.

Response: Existing Federal and non-Federal facilities and their operations are a part of the ''environmental baseline,' as described in the definition (in relevant part): ''The environmental baseline includes the past and present impacts of all Federal, State, or private actions and other human activities in the action area'' (50 CFR 402.02). Commenters are correct that future Federal actions related to Federal or non-Federal facilities may require consultation under section 7(a)(2) of the ESA on the proposed Federal action, including a full analysis of the consequences of the Federal actions and activities caused by the Federal action. If consultation is required under section 7(a)(2) of the Act, it would be subject to the revisions of the implementing regulations at 50 CFR part 402 by this final rule, including revisions to the scope of RPMs. However, it is beyond the scope of this rule to speculate whether that consultation would require RPMs with offsetting measures that are costly or otherwise.

Comment 17: One commenter suggested a revision to the final sentence for ''environmental baseline.'' The commenter recommended changing ''The impacts to listed species or designated critical habitat from Federal agency activities or existing Federal agency facilities that are not within the agency's discretion to modify are part of the environmental baseline.'' to ''The ongoing impacts to listed species or designated critical habitat from existing facilities or activities that are not caused by the proposed action or that are not within the Federal action agency's discretion to modify are part of the environmental baseline.''

Response: The Services decline to accept the suggested edits to the third sentence of the ''environmental baseline'' definition. As we described in the proposed rule, the original sentence inadvertently caused confusion and a focus on the term ''ongoing'' instead of the Federal agency's discretion to modify their own facilities and activities. However, the commenter's suggested language would inadvertently include in the ''environmental baseline'' those facilities and activities that are caused by the proposed action if the Federal agency has no discretion to modify them. Further, the language suggested by the commenter could be read also to include all or portions of the very activities or facilities that are the subject of the proposed Federal action of funding or permitting. Both results would improperly limit the scope of the jeopardy or adverse modification analysis. The Services' definition clarifies that the past and present impacts of existing activities and facilities entirely unrelated to the Federal action in the action area would be in the ''environmental baseline'' whether they are Federal, State, private, or other human activities.

Section 402.16—Reinitiation of Consultation

As proposed, we are revising the text at § 402.16(a) by deleting the words ''or by the Service'' to clarify that the responsibility and obligation to reinitiate consultation lies with the

Federal agency that retains discretionary involvement or control over its action. The text at § 402.16(a) now reads: Reinitiation of consultation is required and shall be requested by the Federal agency, where discretionary Federal involvement or control over the action has been retained or is authorized by law and . . . This revision will not prevent the Services from notifying the Federal agency if we conclude that circumstances appear to warrant a reinitiation of consultation.

Comment 1: Multiple commenters opposed the deletion of the phrase ''or by the Service,'' multiple other commenters supported the removal of ''or by the Service,'' and others noted that the Services are able to provide technical assistance to Federal action agencies when reinitiation is appropriate and requested that the regulations clarify the roles of the Services and action agencies in the ''Reinitiation of Consultation'' section (50 CFR 402.16(a)).

Response: We are removing the language ''or by the Service'' because the sentence as written creates confusion as to the scope of the authorities and roles of the Services relative to the Federal action agency. As explained in our 2019 rule and 2023 proposed rule, only the Federal action agency has the authority and responsibility to initiate or reinitiate consultation when warranted. The Services do not have the power to order other agencies to initiate or reinitiate consultation (*Sierra Club* v. *Marsh,* 816 F.2d 1376, 1386 (9th Cir. 1987); *Defs. of Wildlife* v. *Flowers,* 414 F.3d 1066, 1070 (9th Cir. 2005); 51 FR 19949, June 3, 1986); instead, we are able to recommend that the Federal action agency reinitiate consultation. Because the act of reinitiating consultation is solely the responsibility of the Federal action agency, removing ''or by the Service'' in this portion of the regulations clarifies that responsibility. As noted in the 2023 proposed rule, the Services may still notify the Federal agency if circumstances warrant a reinitiation of consultation. The Services conclude that no additional regulatory language is needed to address this ability.

Comment 2: Two commenters suggested that it would be appropriate to delete § 402.16(b): One believes that the regulations in that paragraph exceed the Services' authority to choose when to reinitiate, and the other believes that identifying only these exceptions is arbitrary. Both stated that § 402.16(b) is ''bad conservation policy.''

Response: Section 402.16(b) was added in the 2019 rule to address issues arising under *Cottonwood Environmental Law Center* v. *U.S. Forest Service,* 789 F.3d 1075 (9th Cir. 2015), and to comport with the Wildfire Suppression Funding and Forest Management Activities Act, H.R. 1625, Division O, which was included in the Omnibus Appropriations bill for fiscal year 2018. The 2018 statute exempted land management plans prepared pursuant to the Federal Land Policy Management Act (FLPMA), 43 U.S.C. 1701 *et seq.,* and the National Forest Management Act (NFMA), 16 U.S.C. 1600 *et seq.,* from reinitiation of consultation when a new species is listed or new critical habitat is designated provided that any authorized actions under the plan that may affect listed species or critical habitat are subject to their own site-specific consultations. We respectfully disagree that § 402.16(b) is ''bad conservation policy'' because the regulations in that paragraph allow the Services to focus our limited resources on those site-specific actions that may cause effects to listed species and designated critical habitat. As we noted in the 2019 rule, the Bureau of Land Management and the U.S. Forest Service (USFS) are required to periodically update their land management plans, at which time they would consult on any newly listed species or critical habitat.

Comment 3: One commenter recommended that reinitiation of consultation because of a new species listing or critical habitat designation be limited to that species or critical habitat, unless one of the other conditions for triggering reinitiation has been met.

Response: Informal or formal consultations that are reinitiated on the basis that the action may affect newly listed species or newly designated critical habitat are, in fact, limited to evaluating the effects of the action on that species or critical habitat, unless another regulatory condition requiring reinitiation applies.

Comment 4: The Services received several comments urging us to make changes to the 2019 regulatory revision clarifying that the duty to reinitiate consultation does not apply to certain existing programmatic land management plans prepared pursuant to the FLPMA or the NFMA when a new species is listed or new critical habitat is designated that may be affected by the plan. Some of the comments maintained that the revision exceeded our authority under the Act and did not support the conservation purposes of the Act.

Response: The Services decline to make changes to the 2019 regulatory revision exempting certain land management plans from the requirement to reinitiate consultation. The 2019 regulatory revision essentially incorporates the exemption (and the statutory conditions for applying that exemption) enacted by Congress in the 2018 Wildfire Suppression Funding and Forest Management Activities Act as part of the 2018 Omnibus Appropriations Act. Although the 2019 regulatory revision extended the exemption to land management plans issued under FLPMA, which were not addressed in the 2018 Omnibus Appropriations Act, the Services disagree that we lack authority to exempt these plans from the reinitiation requirement established by our regulations, not by statute. Because our regulations clarify that the exemption applies only if any action taken under a FLPMA or NFMA land management plan that may affect a newly listed species or newly designated critical habitat can be evaluated in a separate section 7 consultation, we find that this regulatory provision is consistent with ESA section 7 and the overarching conservation purposes of the ESA.

Section 402.17—Other Provisions

As proposed, in this final rule, we are removing § 402.17 in its entirety. This regulatory revision simplifies the regulations and eliminates the need for any reader to consult multiple sections of the regulations to discern what is considered an ''effect of the action.'' The previously articulated basis for § 402.17 will be addressed in an updated Consultation Handbook.

Comment 1: Several commenters disagreed with removal of § 402.17. They supported retaining the requirement that for an activity or consequence to be considered reasonably certain to occur it ''must be based on clear and substantial information.'' The commenters asserted that removing § 402.17 would lead to less clarity and more confusion.

Response: In the proposed rule, the Services articulated several reasons why removing § 402.17 is preferable, including unnecessary confusion and regulatory complexity and potential inconsistency with the statutory requirement to use ''the best scientific and commercial data available.''. These reasons adequately explain why removal of § 402.17 is warranted. First, removing § 402.17 simplifies the structural complexity of the ''effects of the action'' definition. Currently, the term ''effects of action'' is defined in § 402.02, but that definition cross-references § 402.17. Removing § 402.17 would make the ''effects of the action'' definition self-contained within

§ 402.02 without requiring reference to a separate regulatory provision.

Second, section 7(a)(2) of the Act requires both the Federal action agencies and the Services to use ''the best scientific and commercial data available.'' This requirement applies to all aspects of section 7(a)(2), including determining what activities or consequences are considered reasonably certain to occur when analyzing the ''effects of the action'' and any ''cumulative effects.'' The requirement that such analysis must also be based on ''clear and substantial information'' creates an additional standard that could be read to limit what ''best scientific and commercial data available'' the Services may consider. Rather than focusing on the ''best available'' data, the ''clear and substantial information'' requirement would appear to circumscribe that data to only that which meets those heightened requirements.

Third, when read in combination with the preamble discussion in the 2019 final rule that emphasized a need for a ''degree of certitude'' in determining effects of the action that are reasonably certain to occur, § 402.17 could be construed as narrowing the scope of what constitutes the ''best available scientific and commercial data.'' In other words, in light of the ''degree of certitude'' discussion in the preamble of the 2019 rule, § 402.17's ''clear and substantial information'' standard could be read to suggest that even if particular data were considered the best available, they potentially should not be relied upon if they lacked a heightened degree of certitude. The best available data will not always be free of uncertainty and often may be qualitative in nature, and, under the requirements of section 7(a)(2), are to be used by the Services in fulfilling their consultative role under the Act. For these reasons and also as discussed further below, we are removing 50 CFR 402.17 from the section 7 regulations.

Comment 2: Some commenters supported removing § 402.17, particularly the ''clear and substantial information'' standard, asserting that it conflicts with the statute, including the ''best scientific and commercial data available'' requirement, and inappropriately limits the effects analysis.

Response: The Services agree that removing § 402.17 is appropriate for the reasons discussed in this final rule.

Comment 3: Some commenters asserted the Services had not adequately explained how § 402.17 creates the potential for confusion.

Response: The Services' response above and in the preamble of our proposed rule (88 FR 40753, June 22, 2023) explains why § 402.17 has the potential to create confusion. As explained, § 402.17 creates potentially competing requirements between its ''clear and substantial information'' standard and the statutory requirement to use the best scientific and commercial data available. Such competing mandates necessarily contribute to confusion on the part of agencies and applicants who are forced to reconcile them in carrying out their obligations under section 7(a)(2). Additionally, as discussed more fully below, the factors identified in § 402.17, particularly § 402.17(b), are circular in nature, making them potentially unhelpful or confusing as to when an activity is or is not reasonably certain to occur.

Comment 4: As mentioned above, several commenters asserted that the recent *MLA* decision, weighs against the Services removing § 402.17 from the section 7 regulations. They contend that the decision supports the following: the notion that effects must be ''likely'' to occur, the requirement of ''clear and substantial information,'' and limitations on engaging in speculation. They also asserted that the Services should look to the *MLA* decision for direction in any guidance documents the Services develop.

Response: For the reasons discussed above, the *MLA* decision does not undermine the Services' decision to remove § 402.17. To the extent the *MLA* decision raises questions about how the Services resolve uncertainty, the Services reiterate that we will continue to follow accepted scientific methods and evaluate all lines of best available evidence to arrive at principled scientific determinations, including as to what consequences are or are not reasonably certain to occur. This is our longstanding approach to performing the section 7(a)(2) inquiry, and the *MLA* court did not reject this approach. The narrow adverse holding of *MLA* did not speak to the Services' ability to remove § 402.17 from the section 7 regulations for all the reasons stated in the preamble. As with other court decisions, the Services will give appropriate consideration to *MLA* as applicable when developing future guidance.

Comment 5: Some commenters asserted that removing § 402.17 and the requirement of ''clear and substantial information'' is inconsistent with the Act and the best available science standard and would be problematic for consultations that involve assumptions and projections in areas of scientific uncertainty.

Response: As stated above, removing § 402.17 and the ''clear and substantial information'' standard does not change the fundamental ''reasonably certain to occur'' test, which will continue to be applied by the Services in our analyses, including those involving scientific uncertainty. Moreover, the 2019 rule specifically stated that the regulatory changes made in that rule were clarifications and did not ''lower or raise the bar on section 7 consultations,'' and did not ''alter what is required or analyzed during a consultation.'' 84 FR 44976 at 45015, August 27, 2019. While that was the intent of the 2019 rule, for the reasons discussed above, there are concerns that the ''clear and substantial information'' standard itself can cause confusion and could be read to be in tension with the Act's ''best available scientific and commercial data'' requirement. For all these reasons and as discussed throughout, removing § 402.17 is consistent with the Act.

Comment 6: Some commenters urged the Services to retain the factors set forth in § 402.17(a) and (b), rather than address them in a future guidance document.

Response: As stated in the proposed rule, the § 402.17(a) and (b) factors are a non-exclusive list of relevant considerations for determining whether an activity (§ 402.17(a)) or a consequence (§ 402.17(b)) is reasonably certain to occur. Because they are non-exclusive, general in nature, and read more as suggestions than regulatory requirements, they are more appropriately addressed in an update to the Services' Consultation Handbook than in regulatory text. A discussion in the updated Consultation Handbook will lend itself to a more appropriate treatment of these factors and their relevance to identifying activities and consequences that are reasonably certain to occur. Moreover, factors similar to those in § 402.17(a) are already set forth in the Services' original 1998 Consultation Handbook. *See* Services' 1998 Consultation Handbook at 4–32. And while the § 402.17(b) factors (remoteness in time, remoteness in geographic location, and lengthy causal chain) were not specifically discussed in the 1998 Consultation Handbook, the factors themselves are tautological or circular in nature, *i.e.,* each falls back on the concept of what is not reasonably certain to occur to satisfy the factor (*e.g.,* a consequence is too remote in time if it is not reasonably certain to occur). At the same time, this portion of § 402.17 has the potential to

create the misperception that the presence of any of the factors alone indicate that a consequence is not reasonably certain to occur, but the fact that a consequence may be remote in time, for instance, is not dispositive of whether it is not reasonably certain to occur. These potential problems with § 402.17(b) raise the question of whether the factors, in fact, provide much in the way of effective guidance. A more detailed discussion in the updated Consultation Handbook can remedy this potential deficiency.

An additional reason to remove the identified factors is how each set of factors is introduced in the regulatory text. For both § 402.17(a) and (b), they are described as factors to evaluate whether ''activities'' or ''consequences'' are ''caused by the proposed action,'' which is governed by the two-part test of ''but for'' causation and reasonably certain to occur. Yet the factors themselves speak only to what may be considered reasonably certain and ignore what may be relevant for evaluating the ''but for'' prong of the test. While this potential shortcoming might be addressed through further regulatory revision, we believe removal of § 402.17 is the preferred solution for all the reasons stated.

Comment 7: Some commenters supported removing the factors set forth in § 402.17. They asserted that the factors like those found in § 402.17(b) are one-sided and lean only toward negating consideration of certain effects as opposed to also including factors that weigh in favor of considering effects. They assert that such an approach risks inappropriately limiting the effects analysis and species protections, which they consider at odds with the purpose of the ESA. They also question the utility of guidance that might repeat the identified deficiencies.

Response: The Services agree that the removal of § 402.17 is advisable for the reasons stated elsewhere in this final rule. We will take into consideration the commenter's suggestion to potentially broaden the scope of any guidance on factors relevant to what activities or consequences are considered ''reasonably certain to occur'' in developing our updated Consultation Handbook.

Comment 8: Some commenters recommended adding the factors listed in § 402.17(b) as part of the definition of ''effects of the action.''

Response: The Services respectfully decline this suggestion. For the reasons discussed above, we are removing the non-exclusive list of factors in § 402.17(b) from the regulations. Additionally, including these non-exclusive, general factors in the definition of ''effects of the action'' would add unnecessary complexity to the definition.

Comment 9: Some commenters asserted that removing § 402.17 will lead to delays, increased costs for stakeholders, less efficient consultation processes, increased regulatory burdens, and inconsistent outcomes. They also assert that, without § 402.17, the Services would be free to presume consequences regardless of their likelihood or ''degree of certitude.''

Response: We respectfully disagree with the commenters. For the various reasons discussed in this preamble, the Services conclude that removing § 402.17 overall will be more consistent with the Act, resolve potential confusion, and remove regulatory text that is better addressed in an updated Consultation Handbook. As referenced in the preamble of the 2019 rule, the 2019 regulatory changes to the section 7 regulations did not lower or raise the bar on section 7 consultations or alter the scope of analysis. The fundamental test of ''reasonably certain to occur'' remains, which places limitations on the scope of our causation analysis and avoids speculation. To the extent that some commenters are suggesting that one may read § 402.17 to heighten the requirements for determining what activities or consequences are reasonably certain to occur, such heightened requirements (as discussed above) may well be inconsistent with the statutory mandate to use the ''best scientific and commercial data available.'' In particular, the agencies have a fundamental duty to ''insure that any action authorized, funded, or carried out by [an action] agency is not likely to jeopardize the continued existence of a list species.'' 16 U.S.C. 1536(a)(2). Unduly limiting the scope of ''the best scientific and commercial data available'' that an agency may consider could undermine the agency's duty to ''insure''—*i.e.,* ''to make certain,'' *Home Builders,* 551 U.S. at 667—that an action is not likely to jeopardize. Because the fundamental causation test remains, removal of the ''clear and substantial information'' standard will reduce, not increase, confusion. And, we expect the non-exclusive factors set forth in § 402.17 will be addressed and expanded upon in the updated Consultation Handbook. As a result, we do not anticipate removal of § 402.17 will lead to delays, increased costs or regulatory burdens for stakeholders, or less consistent outcomes.

Comment 10: Some commenters expressed a preference for the factors identified in § 402.17(a) and (b) to be addressed in rulemaking rather than guidance. These commenters claimed that rulemaking affords the public with opportunities to comment and requires additional process to revise the regulatory text compared to non-binding guidance. One commenter also asserted the Services should not remove § 402.17 until after public comment on any updated draft Consultation Handbook. Commenters also expressed a concern about how long it will take the Services to issue any updated guidance.

Response: The Services intend to provide an opportunity for public comment on any updated Consultation Handbook, which we anticipate making available after this final rule. Therefore, the public will have an opportunity to review and comment on guidance developed based on the factors identified in § 402.17. While any future Consultation Handbook is not expected to be binding, the non-exclusive, general nature of the factors found in § 402.17 make their regulatory effect to be of, at most, limited import. As for timing, the reasons discussed above explain why it is appropriate to remove § 402.17 now, including the factors of § 402.17(a) and (b). The Services therefore respectfully decline the request to delay their removal.

Comment 11: One commenter opposed the 2019 rule's expansion of the ''reasonably certain to occur'' standard beyond indirect effects and relatedly urged the Services not to adopt guidance perpetuating the expansion. If guidance is necessary on an analytical framework for how to reasonably predict future effects, the commenter urged the Services to adopt an approach similar to the Department of the Interior Solicitor's M-Opinion (Department of the Interior, Office of the Solicitor, Opinion M–37021 (Jan. 16, 2009)) regarding the term ''foreseeable future'' in the context of species listing.

Response: For the reasons discussed in the 2019 rule and elsewhere in this rule, we choose to keep our two-part causation test including ''reasonably certain to occur'' (which collapsed the concepts of direct effects, indirect effects, and interrelated and interdependent activities). Because we are keeping our two-part test, we expect to provide guidance in an updated Consultation Handbook on appropriate considerations. We will consider all credible sources, including the 2009 Solicitor M-Opinion, as we prepare helpful guidance on what is ''reasonably certain to occur.''

Sections 402.02 and 402.14—Scope of RPMs

As proposed, we are revising the definition of ''reasonable and prudent measures'' to adhere more closely to the statute by replacing the term ''believes'' with ''considers'' and replacing the clause ''impacts, *i.e.,* amount or extent, of incidental take'' with ''impact of the incidental take on the species.'' The definition now reads: Reasonable and prudent measures refer to those actions the Director considers necessary or appropriate to minimize the impact of the incidental take on the species. We are also revising § 402.14(i)(1)(i) and (ii) to reflect the above change. To recognize that RPMs are not limited solely to reducing incidental take and may occur outside of the action area, we are also adding the following language to the end of § 402.14(i)(2): ''and may include measures implemented inside or outside of the action area that avoid, reduce, or offset the impact of incidental take.'' Further, we are adding to § 402.14 a new paragraph at (i)(3) to clarify that offsets within or outside the action area can be required to minimize the impact of incidental taking on the species: Priority should be given to developing reasonable and prudent measures and terms and conditions that avoid or reduce the amount or extent of incidental taking anticipated to occur within the action area. To the extent it is anticipated that the action will cause incidental take that cannot feasibly be avoided or reduced in the action area, the Services may set forth additional reasonable and prudent measures and terms and conditions that serve to minimize the impact of such taking on the species inside or outside the action area.

Comments were received on a variety of aspects of the above changes that expand the scope of RPMs but can be grouped under the following two general categories: authority and application.

Authority

Comment 1: Some commenters contended that the Services' proposal allowing for the use of offsets as RPMs conflicts with the plain language of ESA section 7(b)(4)(C)(ii). Specifically, these commenters asserted that ESA section 7(b)(4)(C)(ii) requires RPMs to ''minimize'' the impacts of incidental take rather than to compensate for or eliminate those impacts through offsetting measures.

Response: The Services disagree that the RPM regulatory revision conflicts with the plain language of ESA section 7(b)(4)(C)(ii), and, in fact, assert the opposite. As discussed more fully below, the plain language of section 7(b)(4)(C)(ii) supports the use of offsets as RPMs. The relevant language plainly states that RPMs are to include measures that minimize the impacts of incidental take, not incidental take itself. Like measures that avoid or reduce incidental take, offsetting measures also minimize the impacts of incidental take on the species.

Regarding these commenters' specific assertion that ESA section 7(b)(4)(C)(ii) used the term ''minimize'' rather than ''eliminate'' or ''compensate for,'' these commenters appear to view the use of ''minimize'' as reflecting congressional intent to preclude the Services from using offsets that minimize the impact of incidental taking to the degree that it is eliminated or compensated for. We note, however, that the ordinary meaning of ''minimize'' found in dictionary definitions does not refer to any specific quantum that may be reduced. Some definitions, in fact, indicate that the term means ''[t]o reduce (esp. something unwanted or unpleasant) to the smallest possible amount, extent, or degree.'' *Minimize,* Oxford English Dictionary, *https://www.oed.com/search/dictionary/?scope=Entries&q=minimize* (last accessed on October 26, 2023). The ESA, similarly, does not specify the extent to which impacts are to be minimized. Accordingly, offsets may minimize the impacts of incidental take on the species through measures that counterbalance the loss of individuals taken as a result of the action subject to consultation (*e.g.,* through restoration of habitat anticipated to result in the replacement of the individuals that were taken). Such offsetting measures must be proportional to the impact of incidental take that cannot be avoided or reduced, with the amount or extent of the taking (as described in the incidental take statement) representing the upper limit on the scale of any offsetting measures.

Comment 2: Many commenters maintained that Congress intended offsetting measures to address impacts from incidental take under ESA section 10, not ESA section 7. ESA section 10(a)(2)(B)(ii) authorizes the Services to issue incidental take permits if, among other things, applicants' conservation plans ''minimize and mitigate'' impacts from incidental take. Because ESA section 7(b)(4)(C)(ii), unlike ESA section 10(a)(2)(B)(ii), specifies that RPMs are to ''minimize'' impacts of incidental take, these commenters asserted that Congress did not intend for RPMs to also ''mitigate'' impacts through offsetting measures. These commenters further argued that the proposal allowing for the use of offsets under ESA section 7 impermissibly conflated ''minimize'' with ''mitigate.''

Response: The Services disagree that the statutory criteria for issuing incidental take permits under ESA section 10 indicates that Congress intended to require mitigation from private applicants in the context of section 10, but specifically limited the use of such measures when addressing the *same* impacts in the context of section 7. The plain language of the ESA indicates that Congress considered the terms ''minimize'' and ''mitigate'' to have overlapping meaning when those terms were added as part of the 1982 ESA amendments.

In 1982, when Congress added the provisions for reasonable and prudent measures and ESA section 10 incidental take permits, Congress also revised the process by which a Federal agency, State, or applicant may seek an exemption from the requirement in ESA Section 7(a)(2) to ensure against the likelihood of jeopardy or adverse modification. *See* H.R. Rep. No. 97–56, at 28 (May 17, 1982) and S. Rep. No. 97–418, at 19 (May 26, 1982). Included in the amendments adopted by Congress were additional criteria to be considered by the Endangered Species Committee in granting an exemption. *See* 16 U.S.C. 1536(h)(1) (ESA section 7(h)(1)). Specifically, these amendments provided that the Endangered Species Committee can issue an exemption if, among other things, it ''establishes such reasonable *mitigation* and enhancement measures, including, but not limited to, live propagation, transplantation, and habitat acquisition and improvement, as are necessary and appropriate to *minimize* the adverse effects of the agency action.'' 16 U.S.C. 1536(h)(1)(B) (ESA section 7(h)(1)) (emphasis added). Thus, in the same section of the Act as the RPMs provision, Congress specifically described mitigation measures that offset adverse effects as measures that *minimize* such effects. This provision provides strong support that Congress considered the terms ''minimize'' and ''mitigate'' to have overlapping meaning and that mitigative measures also encompass measures that minimize the impacts of incidental take and vice versa.

This reading of the 1982 ESA amendments is also supported by the ordinary meaning of the terms ''minimize'' and ''mitigate,'' which have a substantial degree of overlap. For example, as mentioned above, the Oxford English Dictionary defines the term ''minimize'' as ''[t]o reduce (esp. something unwanted or unpleasant) to

the smallest possible amount, extent, or degree.'' *Minimize,* Oxford English Dictionary, *https://www.oed.com/search/dictionary/?scope=Entries&q=minimize* (last assessed on October 26, 2023). Similarly, the term ''mitigate'' means ''[t]o alleviate or give relief from (an illness or symptom, pain, suffering, sorrow, etc.); to lessen the trouble caused by (an evil or difficulty).'' *Mitigate,* Oxford English Dictionary, *https://www.oed.com/dictionary/mitigate_v?tab=meaning_and_use#36427497* (last accessed on October 26, 2023).

The Services' view of the proper interpretation of section 10 and section 7 is longstanding. For instance, the Services' position that Congress did not intend for section 10 to establish more rigorous criteria for addressing the same impacts of incidental take than section 7 is found in the preamble to the 1989 rule that finalized revisions to the implementing regulations for addressing incidental take of marine mammals under the Marine Mammal Protection Act and the ESA. *See* Incidental Take of Endangered, Threatened, or Other Depleted Marine Mammals, Final Rule, 54 FR 40338 at 40346, September 29, 1989. In the response to public comments, the Services specifically rejected a comment suggesting that ESA section 10(a)(1)(B) provided for heightened requirements over section 7(a)(2). *See id.* The Services stated the two sections were intended to provide ''the same level of protection for endangered and threatened species.'' *Id.* According to the Services, these comments ''misconstrued the purpose and effect of section 10 provisions relating to private actions'' because they implied that ''private activities are subject to stricter protection standards than activities with Federal involvement.'' *Id.* As the Services further explained, there was ''no indication in the ESA or its legislative history that Congress intended to set up substantially different or stricter protection standards for private activities by requiring a conservation plan.'' *Id.*

For these reasons, section 10's reference to measures that ''minimize and mitigate'' impacts from incidental take should not be read to limit the Services' ability to specify offsets as RPMs to minimize the same impacts in the context of section 7.

Comment 3: We received some comments indicating the Services' current approach that confines RPMs to measures that avoid and reduce incidental take levels proposed is consistent with the legislative history of the 1982 amendments to the ESA.

Response: The Services disagree with these comments. Review of the legislative history of the 1982 ESA amendments demonstrates that Congress considered, but rejected, competing bill language to amend the ESA that would have required reasonable and prudent measures under section 7 and habitat conservation plans under section 10 to minimize ''incidental take,'' rather than minimize the ''impacts'' from incidental take. S. 2309, 97th Cong. section 6(2) (May 26, 1982). As alluded to above, the 1982 ESA amendments changed section 7(b) to include provisions concerning incidental taking of listed species. The new provisions included in sections 7(b)(4) and 7(o)(2) were aimed at addressing a situation in which the Service's biological opinion advises a Federal agency and an applicant (if any) that the proposed action, or the adoption of reasonable and prudent alternatives, will not violate ESA section 7(a)(2), but is still likely to result in taking individuals in violation of ESA section 9. *See* H.R. Conf. Rep. No. 97–835, (1982), *reprinted in* 1982 U.S.C.C.A.N. 2860, 2868 (Federal agencies receiving a favorable biological opinion still may be subjected to citizen suits or civil or criminal penalties for violating section 9 of the Act). To remedy this potential conflict, the 1982 ESA amendments contained an exemption to the ESA's prohibition on ''take'' of listed species for takings that comply with any terms and conditions specified in the incidental take statement to carry out the reasonable and prudent measures required by the Service. *See* 16 U.S.C. 1536(b)(4) (ESA section 7(b)(4)) and 16 U.S.C. 1536(o)(2) (ESA section 7(o)(2)).

The two bills under consideration by Congress in reauthorizing and amending the ESA in 1982 were H.R. 6133 and S. 2309. Both bills were reported out of the respective committees to the full House and Senate with important differences in defining the scope of reasonable and prudent measures. *See* H.R. Rep. No. 97–567 (May 17, 1982) and S. Rep. No. 97–418 (May 26, 1982). As reported out of the House Committee on Merchant Marine and Fisheries, H.R. 6133 contained the language that Congress ultimately adopted in the ESA to describe the scope of reasonable and prudent measures intended to address the impact of the taking on the species: ''those reasonable and prudent measures that the Secretary considers necessary or appropriate to minimize such *impact.*'' H.R. 6133, 97th Cong. section 3(2) (May 17, 1982) (emphasis added).

In contrast, S. 2309, as reported out of the Committee on the Environment and Public Works, explicitly directed that these measures be confined to reducing incidental take. S. 2309, in relevant part, provided ''those reasonable and prudent measures that must be followed to minimize *such takings of such species.*'' S. 2309, 97th Cong. section 6(2) (May 26, 1982) (emphasis added). Unlike H.R. 6133, this Senate bill was explicitly directed at the incidental take itself, rather than the impacts on the species.

In resolving the differences between the House and Senate, the Conference Committee chose the House provisions requiring reasonable and prudent measures to minimize *the impact of the take* on the species, rather than the Senate amendments that restricted the measures to minimizing *the levels of take. See* H.R. Conf. Rep. No. 97–835, (1982), *reprinted in* 1982 U.S.C.C.A.N. 2860, 2868. On September 20, 1982, and September 30, 1982, the Senate and House, respectively, agreed to the Conference Report on H.R. 6133. *See* 128 Cong. Rec. S 11822–24 (September 20, 1982) and 128 Cong. Rec. H 8040–42 (September 30, 1982). H.R. 6133 was subsequently signed by the President and became law on October 13, 1982. *See* Endangered Species Act Amendments of 1982, Pub. L. 97–307, 96 Stat, 1411 (October 13, 1982).

Given that Congress considered and rejected specific language that would have restricted reasonable and prudent measures to activities aimed at reducing incidental take, the legislative history reveals a purposeful choice of Congress in favor of the authority of the Services to select measures that address ''impacts to the species'' from incidental take, rather than confining these measures to reducing incidental take levels *only.* Consistent with this legislative history, all incidental take statements will continue to retain the requirement to describe the amount or extent of incidental take for the purpose of establishing a clear and transparent measure for re-initiating consultation. Thus, impacts on the species, expressed in terms of the amount or extent of incidental take, may be minimized by measures that not only avoid or reduce incidental take levels, but that also offset any residual impacts that cannot be feasibly avoided or reduced. For example, if an incidental take statement quantified the amount or extent of take as the death of 10 individuals of the species and the take of those individuals cannot be avoided or reduced, the Services may minimize the loss of those individuals by specifying offsetting RPMs such as habitat improvements that would result in the anticipated addition of up to 10 individuals

(provided other regulatory requirements are satisfied).

Comment 4: Some commenters questioned why the Services were proposing to change their long-established position that section 7 requires minimization of the level of incidental take and that it is not appropriate to require mitigation for impacts from incidental take. Other commenters noted, however, that no rationale has previously been provided to support restricting RPMs to measures that solely avoid or reduce incidental take levels.

Response: We agree with the comments that observed the sparse rationale underpinning our prior approach in restricting RPMs to avoiding or reducing incidental take within the action area. With this rulemaking, however, the Services take this opportunity to explain why a change is justified.

In over 30 years of practice, we have found that there have been instances in which impacts from incidental take could not be feasibly minimized through measures that avoid or reduce impacts within the action area. In some of those instances, the impacts potentially could have been minimized through offsetting measures, providing a better conservation outcome for the species. Overall, our prior approach of focusing solely on reducing the amount or extent of incidental take within the action area has led to the continued deterioration of the condition of listed species and their habitats and has not sufficiently minimized the impact of incidental take. In recognition that our prior approach was unnecessarily restrictive in carrying out ESA Section 7(b)(4)(ii)'s direction to specify those measures that are ''necessary or appropriate'' to minimize the impacts of incidental take on the species, the Services are, therefore, revising the section 7 implementing regulations to expand the scope of RPMs to allow for the use of offsetting measures. These measures will further minimize the impacts of incidental take caused by the action that cannot be feasibly avoided or reduced. Under this regulatory change, the amount or extent of take described in the incidental take statement will be the maximum level of impacts to minimize.

As explained above, this regulatory revision is based upon a careful review of the Act's text, the purposes and policies of the ESA, and the 1982 ESA legislative history. Based upon that review, we find that this change more fully effectuates the intent of Congress and better serves the conservation goals of the ESA. See, *e.g.,* 16 U.S.C. 1531(b) (describing the conservation purposes of the Act). This regulatory revision will allow the Services to specify measures to offset residual impacts of incidental take that cannot otherwise be feasibly addressed through avoidance and reduction measures. In allowing for residual impacts to be addressed, this revision may reduce the accumulation of adverse impacts to the species that is often referred to as ''death by a thousand cuts,'' which can undermine the Act's overarching goal of providing for the conservation of listed species.

As explained in the proposed rule, this approach for identifying RPMs will also allow the Services to adhere more effectively to the preferred sequence or hierarchy in the development of mitigation. That preferred sequence or hierarchy aims to avoid or reduce impacts to the species first, and then potentially minimize residual impact to the species through offsets.

Comment 5: Several commenters maintained that the proposal allowing for use of offsetting measures as RPMs violates the ''minor change rule,'' which requires RPMs to specify only minor changes that do not alter the basic design, location, duration, or timing of the action. For example, some noted that offsets occurring outside of the action area would necessarily violate the ''minor change rule.''

Response: The Services disagree that the revision allowing for RPMs to consist of offsets violates the ''minor change rule.'' Because, in most instances, they operate as additional measures to minimize impacts of incidental take that cannot be avoided, offsets (regardless of whether they occur within or outside of the action area) would not be expected to result in any modifications that would prevent the action subject to consultation from proceeding as essentially proposed. For example, a consultation on a residential development may include RPMs that offset the take of members of a listed species through contributions to a conservation bank established to repair habitat for that species outside of the action area. In this example, the offset would not result in any changes to the development, including its location, and the development would be able to proceed as planned. On the other hand, RPMs that include measures designed to avoid and reduce incidental take may result in direct changes to the subject action. In the example involving the residential development, for instance, RPMs that specify re-routing an access road to skirt the edge of wetland habitat for a listed species would result in less incidental take. Because the measure directly modifies the design of the residential development, the Services would need to consider whether this change would be ''minor,'' in compliance with the ''minor change rule.'' If the measure would not alter the fundamental design of the development project, the action would go forward as essentially planned, and the change in design would not violate the ''minor change rule.''

Because we do not expect offsetting measures that occur outside of the action area to violate the ''minor change rule,'' we are adopting clarifying language at 50 CFR 402.14(i)(2), which expressly recognizes that offsets may occur within or outside of the action area.

Comment 6: The Services received comments asserting that the proposal relating to RPMs should be carried out under section 7(a)(1), not section 7(a)(2), of the Act. Additionally, one commenter sought specific regulatory changes withholding issuance of an incidental take statement unless the relevant action agency has an ESA section 7(a)(1) conservation program in place for species covered under the subject incidental take statement.

Response: Although section 7(a)(1) and section 7(a)(2) have complementary roles in fulfilling the ESA's conservation goal (see ESA section 2(b)), section 7(a)(1) is not the preferred statutory mechanism to carry out the Services' revision relating to the use of offsets to minimize impacts of incidental take.

The regulatory changes we are adopting in this final rule relating to offsetting RPMs are based on statutory language arising from the process set forth in section 7 for the issuance of biological opinions and incidental take statements, especially section 7(b). Section 7(a)(1) provides separate authority not directly related to these changes. We, therefore, decline the commenters' request.

In addition, the ESA provides no authority for the Services to require Federal action agencies to have a conservation program under ESA section 7(a)(1) as a condition of an incidental take statement. See 16 U.S.C. 1536(b)(4) (setting forth the conditions for issuance of incidental take statements). Therefore, we decline to adopt the commenter's recommendation, as it conflicts with the plain language of section 7(b)(4) of the Act.

Comment 7: The Services received comments that claimed the proposal recognizing the use of offsets as RPMs could violate the Takings Clause of the Fifth Amendment of the United States Constitution. Some of these comments urged the Services to withdraw the

proposal based upon the same concerns raised in the 2018 notice announcing the withdrawal of the 2016 FWS Endangered Species Act Compensatory Mitigation Policy (83 FR 36469, July 30, 2018).

Response: In light of the statutory and regulatory requirements in place for issuing RPMs, the concerns that the use of offsets as RPMs may lead to unconstitutional takings are misplaced. The grounds for withdrawing the 2016 FWS Endangered Species Act Compensatory Mitigation Policy centered on the notion that offsite mitigation raises concerns of whether a sufficient ''nexus'' exists establishing that the relevant impact caused by the specific project proponent (rather than some other actor) is being addressed through the requested mitigation. *See* 83 FR 36469, July 30, 2018. In addition, according to the withdrawal notice, mitigation that adhered to the FWS's policy goal of achieving a ''net conservation benefit'' (which is no longer in effect) could potentially run afoul of Supreme Court precedent requiring ''rough proportionality'' between the government's requested mitigation and the impact being remedied.

Under this revision, however, any offsetting measures, regardless of whether they are applied within or outside of the action area, must be ''necessary or appropriate'' to minimize the impacts of incidental take on the species caused by the action that is subject to consultation. To be in accordance with this statutory requirement, all RPMs (including offsets) must have the requisite nexus between the impacts of incidental take caused by the action and measures that minimize those impacts. In other words, any offsetting measures that are ''necessary or appropriate'' would necessarily target the impacts of incidental take caused by the proposed Federal action, though such offsets may occur in locations that have been subject to impacts from other activities. As previously explained, the Services may minimize the impacts of incidental take by specifying offsetting measures (such as habitat improvements) that would result in the anticipated addition of individuals estimated in the incidental take statement to be taken by the proposed action.

With regard to the concern that mitigation (particularly mitigation with the goal of achieving a ''net conservation gain'') will fail to be proportional to the harm, offsets specified as RPMs must be commensurate with the impact of the incidental taking caused by the action. As explained in the preamble of the proposed rule (88 FR 40753, June 22, 2023), the scale of the impacts from incidental take will serve as the upper limit for the scale of the offset. Importantly, the Services are not specifying RPMs with the goal of achieving ''net conservation gain,'' which was the planning goal referenced in the 2016 FWS Endangered Species Act Compensatory Mitigation Policy but is no longer the goal used by FWS.

Comment 8: Some commenters suggested that the proposal to consider offsetting measures to minimize the impacts of incidental take exceeds the agencies' authority under the ESA. Quoting the decision in *Maine Lobstermen's Association* v. *NMFS,* 70 F.4th 582, 596 (D.C. Cir. 2023), these commenters maintain that Congress intended the Services to have a more limited role under section 7 that involves providing expert assistance to the Federal action agency, rendering an opinion, and if the conclusion is no jeopardy, issuing the incidental take statement.

Response: The Services disagree that the revision recognizing that RPMs may include offsetting measures to minimize impacts of incidental take caused by the action subject to consultation represents a broad expansion of power in contravention of the ESA. The Act plainly authorizes the Services to issue measures that are necessary or appropriate to ''minimize'' the impacts of incidental take. As explained above, offsetting measures, like measures that avoid and reduce incidental take, also minimize the impacts of incidental take on the species.

Under many circumstances, measures that avoid and reduce incidental take will be all that is necessary or appropriate to minimize the impacts of incidental take. However, in those circumstances when impacts from incidental take cannot feasibly be minimized through measures that avoid and reduce incidental take, this revision would allow the Services to consider offsetting measures for inclusion as RPMs. This approach is fully consistent with the Services' statutory authority, and the *MLA* case (which did not address the Services' authority with regard to RPMs) does not stand for a contrary position. For additional discussion of the *MLA* case and the requirements of section 7, please see the discussion of the case at the beginning of the ''Summary of Comments and Responses'' section and the specific discussion relating to the removal of § 402.17 above.

For all the reasons mentioned above, we find that the revision recognizing the use of offsets as RPMs is consistent with the plain language of the Act, a better reflection of Congressional intent, and better serves the conservation goals of the Act.

Comment 9: We received several comments questioning the relationship between the ''minor change rule,'' the Services' mitigation policies, and costs of offsets as RPMs.

Response: Please see our response to comment 5 above regarding the relationship between the ''minor change rule'' and the use of offsets as RPMs. As a matter of practice, when offsetting measures are applicable to a specific formal consultation, the Services will identify potential offsetting measures and work with the action agency (and applicant, if applicable) when developing RPMs (including offsets) to determine, among things, the economic feasibility of these measures. Thus, any costs associated with the offsetting measures would be considered during development of the measure, in coordination with the Federal action agency (and applicant, if applicable), to ensure that the offsetting measure is reasonable and prudent. Measures that are cost-prohibitive in view of the nature of the action may not be considered reasonable and prudent.

With respect to the Services' consideration of their respective mitigation policies, these policies will help inform the development of offsetting measures but will not change the statutory or regulatory requirements that apply to all RPMs. Offsetting measures will be proportionate to the impact of the taking. In addition, monitoring and reporting requirements, as part of the terms and conditions, will continue to be used to verify implementation and efficacy of RPMs, including offsets.

Application

Comment 1: Several commenters questioned how offsets would be developed and state that the relationship of habitat and critical habitat to offsetting measures is unclear. Some commenters asked whether the Services would use habitat types and ratios to determine appropriate offsets.

Response: RPMs that include offsetting measures will be species-specific and will depend upon the factual circumstances surrounding the consultation. Implementing the offsets specified by the Services would be the responsibility of the action agency or applicant. In specifying offsetting measures to minimize the impacts of incidental take, the Services may identify offsetting measures that are implemented through various types of

mechanisms such as conservation banks, in-lieu fee programs, and other kinds of mitigation devices established previously by project proponents. However, any offsetting measures included as RPMs would be designed to minimize the impact of the incidental take resulting from the proposed action to the subject species, and there are scientifically recognized techniques and methodologies that have been used to determine the appropriate level of offsets for species commensurate with the impact of the take to the species. Offsetting measures may consist of purchasing, preserving, or restoring the habitat of the applicable species impacted by incidental take caused by the action. However, offsets do not necessarily have to be applied within critical habitat designated for the relevant species. In addition, RPMs that include offsetting measures may be directed at improving the habitat of the relevant species, regardless of whether the proposed action resulted in impacts to that species' habitat. Offsets may be based on habitat ratios, equivalency modeling, or one-to one replacement, for example. Consistent with the ESA and its implementing regulations, offsets will be necessary or appropriate for minimizing the impacts of incidental take. In all cases, the impact of the take caused by the action, as expressed in the ITS as the amount or extent of incidental take, would provide an upper limit on the scale of any offsetting measures.

Comment 2: Several comments requested information on what specific mechanisms may be used to deliver offsets, and whether these mechanisms may be sponsored by third parties or undertaken by the project proponent.

Response: Some potential mechanisms that could be used to deliver offsets include conservation banks, in-lieu fee programs, and restoration programs. Other mechanisms that may be considered are described in the Services' mitigation policies. Mechanisms that may be considered by the Services could be sponsored by third parties or be the responsibility of the project-proponent. In addition to the Services' mitigation policies that provide guidance in the selection of mechanisms to deliver offsets, the FWS, pursuant to the 2021 National Defense Authorization Act (Pub. L. 116–283), is preparing a rule regarding conservation banking and other mechanisms that, if finalized, will address specific criteria and requirements of those mechanisms to receive FWS approval.

Comment 3: Several commenters expressed concern regarding the lack of existing mitigation banks or in-lieu fee programs for various species or parts of the country, which they contend may result in a delay in completing consultation and implementing their project.

Response: The Services do not anticipate that the lack of available offsetting mechanisms would result in delays to completing consultations in a timely manner or within the statutory or regulatory time frames. The Services understand the current availability of third-party offset mechanisms (*e.g.,* conservation banks and in lieu fee programs) varies greatly across the country and by species, and we will consider the availability of these mechanisms when identifying RPMs. If these mechanisms to deliver offsets are not available, the Services anticipate that such measures would generally not be identified as an RPM. However, more banks and in-lieu fee programs are being established each year as identified in the Regulatory In-lieu Fee and Bank Information Tracking System (U.S. Army Corps of Engineers, *RIBITS: Regulatory In-lieu Fee and Bank Information Tracking System,* last accessed November 8, 2023. *https://ribits.ops.usace.army.mil/ords/f?p=107:2:5966340072209*). Again, the availability of existing mechanisms is one important factor the Services will consider when determining whether measures are necessary or appropriate to minimize the impact of incidental take.

Comment 4: Some commenters recommended avoiding redundant, additional layers of regulation and multiple mitigation mandates.

Response: The Services disagree that the regulatory change to the scope of RPMs will create redundant regulation and additional mitigation mandates. On the contrary, this regulatory change is in alignment with our initiatives to develop efficiencies and holistic approaches to conserving federally listed species. This regulatory change was developed in consideration of existing regulatory frameworks (*e.g.,* Clean Water Act Section 404(b)(1) Guidelines) used by permitting agencies with whom the Services have routinely worked in the conservation of listed species. Mitigation associated with other existing regulatory frameworks is often included in the proposed action by the action agency requesting consultation. The effect of these mitigation measures is considered in the jeopardy analysis and can also minimize the impacts of incidental take caused by the proposed action. When the proposed action includes mitigation measures, there may be no need to include additional offsets as RPMs. As part of the Services' initiatives aimed at leveraging other conservation efforts and building consistency and efficiencies in planning and implementing resource offsets, this regulatory revision promotes conservation at a landscape scale to help achieve the conservation purposes of the ESA. In promoting these purposes, the revision would provide flexibility to the Services to specify measures to address impacts from incidental take that cannot be feasibly addressed through measures that avoid or reduce incidental take. As mentioned in the preamble of the proposed rule (88 FR 40753, June 22, 2023), impacts from incidental take that are not addressed can accumulate over time, potentially leading to more severe impacts on the species (sometimes referenced as ''death by a thousand cuts''). In addition, to the extent that RPMs may not be feasible within the action area, this revision provides the flexibility to specify measures within locations outside of the action area that serve as important corridors for species survival, reproduction, or distribution, providing benefits to the species on a landscape scale.

Comment 5: A few commenters asked for clarification or a definition of the term ''feasibly'' proposed in the RPM regulatory revisions at 50 CFR 402.14(i)(3): To the extent it is anticipated that the action will cause incidental take that cannot feasibly be avoided or reduced in the action area, the Services may set forth additional reasonable and prudent measures and terms and conditions that serve to minimize the impact of such taking on the species inside or outside the action area.

These commenters requested the Services describe the circumstances under which the Services will determine that the impacts of the agency action ''cannot feasibly'' be ''avoided or reduced'' within the action area.

Response: The term ''feasibly'' should be understood to have the same ordinary meaning found in the dictionary definition of that term. For instance, ''feasibly'' is the adverb form of the term ''feasible,'' which means ''[o]f a design, project, etc.: [c]apable of being done, accomplished or carried out; possible, practicable''. *Feasible,* Oxford English Dictionary, *https://www.oed.com/search/dictionary/?scope=Entries&q=feasible* (last accessed on November 5, 2023). We, therefore, do not find that a regulatory definition is needed. The Services may find measures that avoid or reduce incidental take cannot feasibly minimize the impacts of incidental take when such measures would violate the

''minor change rule.'' Or, in some cases, the Services may determine that specifying measures that avoid or reduce incidental take within the action area as RPMs would not be feasible because the degraded condition of the area would require cost prohibitive measures that are not reasonable and prudent. Under these types of limited circumstances, the Services may consider minimizing the impacts from incidental take caused by the proposed action through offsetting measures that occur within or outside of the action area.

Comment 6: We received several comments related to the preferred order of RPMs and a request for clarification of the term ''priority.'' Many commenters supported a preferred order/hierarchy, while others wanted more flexibility.

Response: Under this regulatory change expanding the scope of RPMs, the Services will place a priority on measures that avoid or reduce incidental take over offsetting measures. In recognition of the Services' preference to specify measures that prevent incidental take from occurring in the first instance, we will first consider measures that avoid or reduce incidental take in the action area. See 88 FR 40753, June 22, 2023. If impacts from incidental take cannot be feasibly minimized through measures that avoid or reduce incidental take, the Services will then consider offsetting measures to minimize the residual impacts of incidental take in the action area. After considering whether offsetting measures can feasibly be applied within the action area, the Services may then consider specifying offsets outside of the action area to minimize the impacts of incidental take caused by the action subject to consultation. In summary, the steps are as follows:

1. Avoid or reduce, within the action area, the impact of incidental taking on the species.
2. Offset, within the action area, the impact of incidental taking on the species.
3. Offset, outside the action area, the impact of incidental taking on the species.

Comment 7: One commenter stated that the determination of whether offsetting RPMs are or are not reasonably available in the action area may depend in part on whether the action area is broadly or narrowly defined and how well the site-specific effects of the proposed Federal action are identified and analyzed in the biological opinion. The commenter asked the Services to clarify how they will ensure that an action area is properly drawn and keyed to the actual impacts of the agency action and that the effects of the action are properly analyzed at a site-specific level, to minimize the potential for arbitrary determinations that off-site mitigation is necessary.

Response: The Services do not define the action area broadly or narrowly for the purpose of ensuring that RPMs are available in the action area. In accordance with the regulatory definition of ''action area,'' the action area must be based upon the specific action subject to the consultation and must consist of ''all areas to be affected directly or indirectly by the Federal action and are not merely the immediate area involved in the action.'' 50 CFR 402.02. The Services did not propose any changes to the definition of ''action area'' or the process of defining it. Thus, the Services will continue to ensure that an action area is properly drawn and keyed to the actual impacts of the agency action and that the effects of the action are properly analyzed within the defined action area. Regarding application of offsetting measures, the Services clarify that offsetting measures could be included as RPMs inside and outside the action area. As previously explained in comment 6 above, the Services will follow a preferred sequence for developing RPMs that is set forth in § 402.14(i)(3) of the implementing regulations. Under this preferred order for specifying RPMs, we anticipate that offsetting measures outside of the action area will be specified under limited circumstances when, for instance, RPMs within the action area would violate the ''minor change rule'' or would not be economically or technologically feasible.

Comment 8: Several commenters requested additional detailed information on the specific timing for implementing offsetting measures to minimize the impacts of incidental take.

Response: Ideally, offsetting measures would be implemented in advance of the impact from the action occurring in order to reduce risk and uncertainty and reduce the temporal impacts from incidental take. However, the timing of implementation will be determined on a case-by-case basis and will depend upon various factors such as the availability of existing mechanisms to offset impacts from incidental take (*e.g.,* conservation banks) and the best scientific and commercial data available.

Comment 9: Several commenters requested additional detailed information on the location of offsetting measures outside of the action area.

Response: As stated above, the specific location of offsetting measures will be determined on a case-by-case basis and will depend upon various factors such as the availability of existing mechanisms to offset impacts from incidental take and the best scientific and commercial data available.

Comment 10: Many commenters supported the application of RPMs outside the action area when such application would create efficiencies and be beneficial.

Response: The Services appreciate the commenters' support, and we agree that the regulatory change allowing for the application of RPMs outside the action area will provide additional conservation benefits to affected species and create efficiencies in extending these benefits. For example, additional benefits would be provided to the affected species when measures that avoid or reduce incidental take could not feasibly be applied. The regulation can also create efficiencies by using established mechanisms to deliver offsets, such as specifying the purchase of an offsetting credit from a conservation bank already established and approved in connection with a habitat conservation plan (HCP).

Comment 11: One commenter expressed concern that allowing RPMs to go outside the action area may be in conflict with County, State, and Tribal mitigation programs that require offsets to be implemented locally.

Response: As stated previously, all RPMs must be reasonable and prudent and within the authority of the action agency to implement. If there are laws that apply to the proposed action that require all mitigative measures to be located within a specific geographic area (locally) and offsetting measures outside of that area would violate those legal restrictions, then the offsets would not be within the action agency's (or applicant's) authority to implement.

Comment 12: One commenter contends that offsetting measures should not be required for biological opinions that use surrogates to express the amount or extent of anticipated take because it is hard to determine if take even occurs since the ''reasonable certainty'' standard does not require a guarantee that take will occur.

Response: The Services decline to adopt the commenter's suggestion to exclude the use of offsetting measures when a surrogate is used to express the amount or extent of the taking caused by the action. This suggestion conflicts with the ESA's requirement to specify RPMs that are necessary or appropriate to minimize the impacts of incidental

take on the species. The implementing regulations governing the use of surrogates in estimating the amount or extent of incidental take is found at § 402.14(i)(1)(i). When using surrogates, the Services are required to ensure they establish a clear standard for determining when the level of anticipated take has been exceeded. Because many offsetting measures are likely to be habitat-based and the Services often use impacts to habitat as a surrogate for estimating the amount or extent of incidental take, the metrics used to identify a surrogate can be useful and appropriate for establishing offsetting measures as RPMs. For example, if a surrogate for take of a cryptic listed insect is identified by the number of host trees lost that the species uses for reproduction and survival, measures to conserve the amount of host trees lost due to the action could also serve as offsetting RPMs.

Comment 13: Some commenters stated that monitoring and reporting on the implementation of the offsetting measures is needed.

Response: As with all incidental take statements, monitoring and reporting are required parts of the terms and conditions to implement RPMs, pursuant to ESA section 7(b)(4)(iv) and its implementing regulations. This statutory and regulatory requirement would still apply to the terms and conditions to carry out offsetting measures, and this rulemaking does not make any changes to that requirement. Regardless of whether third-party mitigation arrangements or project proponent mitigation is used, these mechanisms for delivering offsets must satisfy any monitoring and reporting requirements contained in the terms and conditions of the incidental take statement.

Comment 14: Some commenters requested that specific actions be excluded from the Services' ability to impose additional RPMs that offset impacts. One example mentioned by commenters as warranting exclusion from imposition of additional RPMs involves consultations on habitat restoration projects that have net benefits to habitat functions or services.

Response: Identifying specific types of actions for exclusion in this rulemaking may be in conflict with the requirements of section 7 and cannot be predicted in advance. Thus, we decline to specify such actions. However, in practice, the Services have found that project proponents of these types of specific actions often voluntarily include measures that minimize the impacts of incidental take, potentially eliminating the need for additional RPMs.

Comment 15: One commenter stated they ''oppose perpetual offsets in situations where a species is not meeting recovery goals and there is not a clear or quantifiable link to pesticides as a stressor.''

Response: We interpret that this commenter intended to oppose offsets that are perpetual in nature for species in decline and offsets that are not directly linked to the amount or extent of incidental take identified in the incidental take statement. However, it is important to note that RPMs are required to be ''necessary or appropriate'' to minimize the impacts of incidental take that is reasonably likely to occur from the proposed action. To be in accordance with these statutory and regulatory requirements, all RPMs (including offsets) must have the requisite nexus between the impacts of incidental take caused by the action and the measures that minimize those impacts. Thus, offsetting measures, as with all RPMs, would not address impacts caused by other activities that are not the subject of the consultation. RPMs, including offsets (if appropriate), whether perpetual or not, will be determined on a case-by-case basis.

Comment 16: Several commenters asked for sideboards that limit the extent of offsetting measures and how the Services will minimize uncertainty, prevent inconsistency, and ensure that offsetting RPMs are not arbitrary. Other commenters stated that offsets should achieve a ''no net loss,'' or even a net gain, with no upper limit.

Response: As explained in the preamble of the proposed rule (88 FR 40753, June 22, 2023) and elsewhere in this final rulemaking, there are several statutory and regulatory standards that will govern the application of offsetting measures. First, only after fully considering measures that will avoid or, reduce incidental take would the Services consider specifying measures that offset the residual impacts of incidental take that cannot feasibly be avoided. In most cases, measures that avoid or reduce incidental take within the action area will be preferred in minimizing the impacts of incidental take, consistent with the preferred sequence at 50 CFR 402.14(i)(3) and as further described in the response to comment number 6 above.

Second, the Services will coordinate as appropriate with the action agency and applicant, if any, on development of offsetting measures. As always, this coordination is essential to ensure that RPMs are within a Federal action agency's, and applicant's (if any), authority or discretion to implement. All RPMs, including offsetting measures, must be reasonable and prudent; any RPMs, including those consisting of offsetting measures, that are not within a Federal action agency's, and applicant's (if any), authority or discretion to implement would not be reasonable and prudent. Measures that are cost-prohibitive may also not be reasonable and prudent to minimize the impacts of incidental take.

Third, the impact of the incidental take on the species caused by the action will provide the upper limit on the scale of any offsetting measures. Only offsetting measures that are necessary or appropriate to minimize the impacts of incidental take will be specified as RPMs. Thus, RPMs, including those consisting of offsetting measures, will be proportional to the impacts of incidental take caused by the action and not be required to provide a net benefit to the species.

Fourth, as with all RPMs, monitoring and reporting requirements will be required as part of the terms and conditions of the ITS.

Lastly, this revision to the scope of RPMs does not change the Services' long-standing practice of working with Federal action agencies and applicants in developing ''conservation measures,'' as defined in the 1998 Consultation Handbook, that may be voluntarily incorporated as part of the ''action'' to minimize adverse effects. In fact, the Services have a long history of working with Federal action agencies and applicants to develop these voluntary measures, some of which include offsets, to produce strong conservation outcomes. The Services' expertise gained in developing offsetting measures that may be incorporated as part of the action will be used in the development of offsets included as RPMs.

Comment 17: We received comments questioning whether offsetting RPMs would be applied to consultations on listed plant species and critical habitat.

Response: As with all RPMs, RPMs that consist of offsets, are specified to minimize the impacts of incidental take of wildlife (not plants or critical habitat) caused by the action. Because incidental take statements are issued only for incidental take of wildlife, this regulatory revision allowing for offsetting measures as RPMs would not apply to plants or critical habitat.

Comment 18: Several commenters shared concerns regarding the costs of offsetting measures. Some stated the costs would be significant to the regulated community and some stated

the cost is unpredictable, but the range of potential costs is substantial.

Response: Offsetting measures, as with all RPMs, do have an associated cost. However, we anticipate offsetting measures will be used in limited circumstances. For example, most consultations are completed informally, and this regulation would apply only to formal consultations that require an ITS containing RPMs. Even among formal consultations that require an ITS containing RPMs, some of these consultations will be able to address impacts of incidental take through measures that avoid or reduce incidental take within the action area, and offsets would be considered only if measures that avoid or reduce incidental take cannot feasibly minimize the impacts of incidental take caused by the proposed action. Although we anticipate that offsetting measures will be used under limited circumstances when measures that avoid or reduce incidental take cannot feasibly be applied, it is not possible to know how many formal consultations will include offsetting measures as RPMs due to the tremendous variation in Federal actions subject to formal consultation, the specific impacts from these actions, and the affected species that may be analyzed.

Although we cannot predict the costs of the RPM proposal due to these variable factors associated with formal consultations, any costs would be constrained by the statutory and regulatory requirements that RPMs are ''necessary or appropriate,'' commensurate with the residual impacts of incidental take caused by the proposed action. In addition, as previously mentioned, the Services consider the economic feasibility of any RPMs.

All Other Aspects of the 2019 Rule

As stated earlier, the proposed rule also sought comment on all aspects of the 2019 rule. Although the vast majority of the comments received on all other aspects of the 2019 rule were non-substantive, we did receive substantive comments and other relevant comments warranting response on the topics of the definition of ''destruction or adverse modification,'' programmatic consultations, non-Federal representatives, § 402.13(c)(2) informal consultation timelines, § 402.14(h)(3) and (4) adoption of analysis, section 7(a)(1) (programs for the conservation of listed species), project modifications, the geographic scope of section 7(a)(2), and ''small Federal handle.'' Our responses to the comments on these topics and others are provided below.

Destruction or Adverse Modification

Comment 1: Commenters request the removal of the phrase ''as a whole'' from the definition of destruction or adverse modification. These commenters assert that the phrase undermines conservation and recovery of species because it would allow more piecemeal, incremental losses of critical habitat over time that would add up cumulatively to significant losses or fragmentation (referred to by many comments as ''death by a thousand cuts''). Furthermore, they contend the phrase ''as a whole'' limits the Services' ability to analyze impacts and lacks scientific justification.

Response: As discussed in the 2019 rule (see 84 FR 44976 at 44983–44985, August 27, 2019), the Services again decline to remove the phrase ''as a whole'' from the definition of destruction or adverse modification. The definition of ''destruction or adverse modification'' is focused first on the critical habitat itself, and then considers how alteration of that habitat affects the ''conservation'' value of critical habitat. The phrase ''as a whole'' will not reduce or alter how the Services consider the effects of small changes to critical habitat. This approach is fully consistent with the nature of critical habitat and the duty to avoid destruction or adverse modification of critical habitat under the Act, as well as the scientific principles underlying those provisions.

Additionally, this approach does not limit our ability to analyze impacts to critical habitat using the best available scientific and commercial information. As discussed in the 2019 rule, consistent with longstanding practice and guidance, the Services must place impacts to critical habitat into the context of the entire designation to determine if the overall value of the critical habitat is likely to be appreciably reduced, but this consideration does not mean that the entirety of the designated critical habitat must be affected by the proposed action. This situation could occur where, for example, a smaller affected area of habitat is particularly important for the conservation of a species (*e.g.,* a primary breeding site). Thus, the size or proportion of the affected area is not determinative; impacts to a smaller area may in some cases result in a determination of destruction or adverse modification, while impacts to a large geographic area will not always result in such a finding.

Moreover, with regard to concerns of ''death by a thousand cuts,'' the regulations require the Services' biological opinion to assess the status of the critical habitat (including threats and trends), the ''environmental baseline'' of the action area, and cumulative effects. The Services' summary of the status of the affected species or critical habitat considers the historical and past impacts of activities across time and space for the entire listed entity and critical habitat designation. In this context, the effects of any particular action and ''cumulative effects'' are added to those impacts identified in the ''environmental baseline.'' This analytical process avoids situations where each individual action, when viewed in isolation, may cause only relatively minor adverse effects but, over time, accumulated effects of these actions would erode the conservation value of the critical habitat. In the 2019 rule, we clarified the text in § 402.14(g)(4) regarding status of the species and critical habitat to better articulate the analytical process used to determine whether an action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat. The clarification helped to ensure the ''incremental losses'' described by the commenters are appropriately considered in our jeopardy and ''destruction or adverse modification'' determinations.

Comment 2: Some commenters asserted that inclusion of ''as a whole'' in the definition of destruction or adverse modification is inconsistent with case law.

Response: None of the cases cited favorably by commenters directly address the issue of the appropriate scale of the ''destruction or adverse modification'' analysis. And while commenters may disagree with the holding, the Ninth Circuit Court of Appeals has specifically endorsed the approach of analyzing the impacts to critical habitat at the scale of the entire designation. *See Butte Envtl Council* v. *U.S. Army Corps of Eng'rs,* 620 F.3d 936, 947–48 (9th Cir. 2010) (citing the Services' 1998 Consultation Handbook at 4–34).

Comment 3: Some commenters asserted that inclusion of ''as a whole'' does not adequately afford protection to critical habitat of species that are wide-ranging and migratory.

Response: As discussed above, the Services' approach to analyzing impacts to portions of a critical habitat provides a full assessment of individual actions by relying on the jeopardy and

destruction/adverse modification framework. That framework considers the overall status of the critical habitat, and in that context, adds the effects of any particular action and any ''cumulative effects'' to those impacts identified in the ''environmental baseline.'' Thus, under this analytical framework, incremental impacts from prior actions are not ignored, and the overall conservation value of critical habitat is appropriately preserved for the benefit of the listed species. This same framework applies to species with expansive critical habitat designations and ensures any impacts to particular areas are appropriately considered within the context of the respective critical habitat designation as a whole.

Programmatic Consultation

Comment 1: One commenter requested revision of the definition of ''programmatic action'' to clarify whether programmatic consultations are required, how programmatic consultations can be used, and the roles of multiple Federal agencies, and of non-Federal applicants.

Response: Given the nature of programmatic consultation and the significant flexibilities provided by section 7 of the ESA, additional details regarding the specifics and scope of programmatic consultation are better addressed through updates to the Consultation Handbook rather than additional regulatory text. The current definition of ''programmatic consultation'' is quite broad and covers a broad suite of actions that could constitute a program, plan, policy, or regulation providing a framework for future proposed actions. *See* 50 CFR 402.02. Although broad, the examples of actions included in the definition are not intended to identify every type of program or set of activities that may be consulted on programmatically. The programmatic consultation process offers great flexibility and can be strategically developed to address multiple listed species and multiple Federal agencies, including applicants as appropriate, for both informal and formal consultations. We encourage Federal agencies and applicants to reach out to the Services to discuss the potential ways to structure a consultation (such as the use of programmatic consultations) to streamline the consultation process.

Non-Federal Representative

Comment 1: One commenter suggested agencies allow the developer to be designated as a ''non-federal representative'' for purposes of consultation to prepare the biological assessment and hold pre-application meetings. The commenter also suggested that NMFS help with communication and resolving fundamental questions.

Response: Regulations at 50 CFR 402.08 allow a Federal agency to designate a non-Federal representative for conducting informal consultation or preparing a biological assessment. The Services may provide technical assistance to the non-Federal representative, in coordination with the Federal action agency, to address questions regarding the consultation process, but the section 7(a)(2) consultation responsibility ultimately lies with the Federal action agency.

Section 402.13(c)(2)—Informal Consultation Timelines

Comment 1: Some commenters advocated for the removal of the 60-day timeline in § 402.13(c)(2). Those commenters stated that according to information included in the preamble to the 2018 draft revisions, only 3 percent of informal consultations take more than 3 months to complete, and therefore there is no rational justification to adopt a timeline to address this low number of informal consultations, nor is there reason to believe that this small number of informal consultations lasting longer than 3 months causes a problem for action agencies. The commenters ask the Services to focus on addressing the small number of lengthier informal consultations rather than imposing an across-the-board timeline.

Response: The Services are retaining the 60-day timeline for issuing a concurrence or non-concurrence for informal consultations. The Services' intention with this timeline is to increase regulatory certainty and timeliness for Federal agencies and applicants. Based upon more than 3 years of implementing this provision, the Services find that the 60-day timeline is justified to promote the goals of increasing regulatory certainty and timeliness. As stated in the preamble and response to comments in the 2019 rule, the 60-day timeline begins only after receipt of information sufficient for the Services to determine whether to concur. See § 402.13(c)(2) (requiring information similar to the types of information needed to initiate formal consultation). The Services typically review all initiation request packages within 30 days. In addition, should more time be required for the Services' determination, § 402.13(c)(2) provides for a 60-day extension upon mutual consent. We anticipate that this provision will continue to provide greater certainty for Federal agencies and applicants, while ensuring that the Services have sufficient information and time to reach an informed decision. Finally, we have not experienced problems in practice with § 402.13(c)(2) under the 2019 rule; this provision's assurances for regulatory certainty and timeliness outweigh any concerns with implementation.

Section 402.14(h)—Adoption of Analysis

Comment 1: Some commenters expressed concern that the 2023 proposed regulations make no change to the 2019 revisions at 50 CFR 402.14(h)(3)(i) allowing the Services to adopt, as part of their biological opinions, all or part of a Federal action agency's consultation initiation package. These commenters claim that in doing so the Services abdicate their statutory consultation duty in violation of ESA section 7(b)(3)(A) (requiring the Services to issue an opinion to the action agency).

Response: The Services disagree that adoption of part or all of the information in an action agency's initiation package, including biological analyses, violates the ESA. Furthermore, under the provision, the Services will not indiscriminately adopt analyses or documents from non-Service sources. Rather, the Services perform their statutory consultative function, adopting analyses provided in the initiation package only after we have conducted an independent evaluation to determine whether the analyses meet statutory and regulatory requirements, including the requirement to use the best scientific and commercial data available. As we expressed in our response to comments on the proposed rule to the 2019 rule, the intent of this provision is to avoid needless duplication of analyses and documents that already meet applicable statutory and regulatory standards. In some situations, the Services may supplement or revise these analyses or documents to merit inclusion in our letters of concurrence or biological opinions, but even in those situations, adopting useful existing information makes the consultation process more efficient and streamlined.

In the 2019 rule, we explained that it was already common practice for the Services to adopt portions of biological analyses and initiation packages in our biological opinions. The codification of that practice created a more collaborative process and incentive for Federal agencies to produce high-quality analyses and documents suitable for inclusion in biological opinions, which streamlines the timeframe for

completion of the consultation. The Services continue to exercise their independent judgment and biological expertise in reaching conclusions under the ESA.

Comment 2: Commenters representing the pesticide manufacturing and end user communities remained supportive of those provisions of § 402.14(h)(3) and (4) allowing for a collaborative process and the adoption of biological analyses provided by action agencies, explaining that adoption of such analyses produced by the Environmental Protection Agency (EPA) would further increase collaboration between the Services and Federal action agencies, consistent with the commenters' long-standing advocacy for greater coordination in this vein.

Response: We agree that § 402.14(h)(3) and (4) continue to add value by promoting increased collaboration and allowing for the adoption of biological analyses provided by a Federal agency, where appropriate and in line with the Services' scientific standards. The Services are maintaining these provisions, as they further expediency, collaboration, and the use of sound science.

Section 402.14(l)—Expedited Consultation

Comment 1: Some commenters advocated for the removal of 50 CFR 402.14(l), which provides for the Services to enter into expedited consultation upon mutual agreement with a Federal agency. Commenters argued that the Services provided no evidence to support the claim in the 2019 rule that the new expedited process ''will benefit species and habitats by promoting conservation and recovery through improved efficiencies in the section 7 consultation process,'' or ''will still allow for the appropriate level of review.'' 84 FR 44976 at 45008, August 27, 2019. Commenters noted that the Services provided only one example of an action that could benefit from expedited consultation and included no qualifying criteria for such projects. The commenters express concern that a lack of guidelines on when to apply this provision will cause confusion and arbitrary application of the regulation.

Response: The Services' intention in retaining § 402.14(l) is to allow for an optional process that is intended to streamline the consultation process for those projects that have minimal adverse impact but still require a biological opinion and incidental take statement and for projects where the effects are either known or are predictable and unlikely to cause jeopardy or destruction or adverse modification. As we explained in our response to comments in the 2019 rule, many of these projects historically have been completed under the routine formal consultation process and statutory timeframes, and this provision will expedite the timelines of the formal consultation process for Federal actions while still requiring the same information and analysis standards. While less time may be necessary to analyze projects that fit under the provision due to their primarily beneficial nature or their known and predictable effects, the Services must still apply all required analysis to the actions under consideration. We simply expect that given the nature of the actions, a streamlined process would allow for a better use of our limited resources, yet still be consistent with section 7 of the ESA.

The Services have not included specific qualifying criteria for expedited consultations because there is a range of different actions or classes of actions that may qualify. Acceptance into expedited consultation will require the exercise of independent judgment and discretion on the part of the Services for each such request. We also note, as we expressed in our response to comments on the 2019 rule, that a key element for successful implementation of this process is mutual agreement between the Services and Federal agency (and applicant when applicable). The mutual agreement will contain the specific parameters necessary to complete each step of the process, such as the completion of a biological opinion.

The Services strive to complete consultations within the established regulatory deadlines and continue to identify ways to improve efficiencies. Section 402.14(l) provides one such streamlining mechanism intended to improve efficiencies in the section 7(a)(2) consultation process for the Services, Federal agencies, and their applicants while ensuring full compliance with the responsibilities of section 7. One example of an expedited formal consultation process agreed to by the FWS and the USFS is the programmatic consultation for the Rangewide Conservation Activities Supporting Whitebark Pine Recovery Project (Project). The Project includes ongoing and future activities proposed by the USFS to support the conservation of federally threatened whitebark pine (*Pinus albicaulis*) across its range, specifically cone collection, scion collection, pollen collection, operational seedling production, genetic white pine blister rust screening, planting, insect prevention and control, selection and care of mature trees with white pine blister rust resistance, protection of healthy and unsuppressed regenerating stands, clone banks, seed and breeding orchards, genetic evaluation plantations, development of seed production areas, surveys, and research, monitoring, and education. While these activities are intended to be beneficial to whitebark pine, some adverse effects are anticipated to occur because of the Project. This expedited consultation process reduced the consultation timeline allowing beneficial actions to move forward more quickly.

Comment 2: Commenters representing the pesticide manufacturing and end user communities remained supportive of those provisions of § 402.14(l) allowing for expedited consultation and encourage the Services to work with Federal agencies to streamline initiation packages by using templates and guidance. Commenters also requested the Services reconsider and re-promulgate 50 CFR part 402, subpart D, regarding pesticide consultations, following adverse litigation.

Response: The Services agree that the expedited consultation provisions of § 402.14(l) are a potentially valuable tool for creating efficiency in the consultation process, including efficiencies that could potentially be applied in pesticide consultations. We will continue to work with Federal action agencies and applicants to help them develop strong biological analyses that can allow for expedited consultation. We acknowledge the commenters' request for reconsideration of subpart D, which was not the subject of any regulatory changes in the 2019 rule and thus outside the scope of this rulemaking. Any such changes would require a separate rulemaking process, which would first require careful consideration and consultation with the EPA and others.

Section 7(a)(1) of the ESA

Comment 1: Some commenters requested that the Services develop and finalize implementing regulations for section 7(a)(1), which requires Federal agencies in consultation with the Services to utilize their authorities to establish programs for the conservation of listed species.

Response: At this time, because there are no implementing regulations for section 7(a)(1), the Services expect to include guidance on section 7(a)(1) in an updated Consultation Handbook and develop additional guidance as necessary. We recognize there are opportunities for Federal action agencies to proactively support species conservation, consistent with their

authorities, and we anticipate that providing additional guidance regarding section 7(a)(1) will help further those efforts.

Project Modifications

Comment 1: One commenter raised issues related to project modifications that happen during a consultation, as well as once consultation has been completed and a biological opinion or letter of concurrence has been issued. The commenter requested that consultation continue even if a proposed action has been modified and that changes in the action could be reflected in future consultations as part of the ''environmental baseline.'' The commenter also requested that the Services indicate that no further consultation would be needed if an action was subsequently modified in such a way that does not increase the amount or extent of incidental take.

Response: The Services note that the commenter's request relates to the existing regulations regarding reinitiation of consultation at § 402.16. As the commenter noted, criteria exist for the reinitiation of completed consultations with issued biological opinions or letters of concurrence: These include whether incidental take is exceeded; if new information reveals effects of the action that may affect listed species or critical habitat in a manner or to an extent not previously considered; if the identified action is subsequently modified in a manner that causes an effect to the listed species or critical habitat that was not considered in the biological opinion or written concurrence; or if a new species is listed or critical habitat designated that may be affected by the identified action.

These criteria are independent of one another; thus, modification of the action may trigger reinitiation of an already completed consultation if the manner of effects changes, even when the extent of those effects is not greater. This determination is case-specific, and it is beyond the scope of this rule to state that only those cases where anticipated incidental take is exceeded would trigger reinitiation.

The commenters also provide an example of a consultation that was restarted due to modification of the proposed action as a result of ''new'' information. With regard to changes to the action or new information that arises during a pending consultation, the Services typically coordinate with the action agency and any applicant to determine the significance of any change or new information and the needed response. Although case specific, the responses range from minor supplements to the existing initiation package to withdrawal and resubmittal of the entire package. This practice ensures the final concurrence letter or biological opinion is based on up-to-date information, including a correct description of the proposed action.

Geographic Scope of Section 7(a)(2)

Comment 1: One commenter suggested the Services revise 50 CFR part 402 to restore the full geographic scope of the Services' implementation of the ESA with respect to consultations under section 7 of the Act.

Response: This request is beyond the scope of the proposed rule and would require a new rulemaking process. The current geographic scope of the section 7 regulations as reflected in the definition of ''action'' is appropriate, and the Services do not anticipate revisiting this issue. *See* 50 CFR 402.02; 51 FR 19926 at 19930–31, June 3, 1986 (discussing geographic scope of section 7 of the ESA).

Small Federal Handle

Comment 1: One commenter suggested that the Services promulgate regulations clarifying the scope of ''small Federal handle'' projects affording project proponents input into whether to become part of a consultation where the Federal agency has only limited authority over significant aspects of a larger project.

Response: The Services decline to adopt regulations clarifying the scope of ''small federal handle'' projects. As discussed in the 2019 rule, when the Services write an incidental take statement for a biological opinion under section 7(b)(4)(iv) of the Act, they can assign responsibility for specific terms and conditions of the incidental take statement to the Federal action agency, the applicant, or both, taking into account their respective roles, authorities, and responsibilities. The Services have worked with Federal action agencies in the past, and will continue to do so into the future, to ensure that a reasonable and prudent measure assigned to a Federal action agency does not exceed the scope of a Federal action agency's authority.

Other Comments

Comment 1: One commenter suggested changing the regulatory threshold for consulting on federally listed plant species to only situations where the project is likely to jeopardize the listed plant.

Response: The commenter misconstrues the consultation regulations, and no regulatory change is needed. The purpose of consultation is for the Services to assist the Federal agency in meeting their obligation to ensure their action is not likely to jeopardize the continued existence of listed species or destroy or adversely modify designated critical habitat. Consultation is the process by which the Services determine whether the action is likely to jeopardize the listed plant.

Comment 2: One commenter suggested revisions that would allow applicants to choose their method of ESA compliance through a programmatic HCP to take advantage of the streamlining opportunity it provides rather than being directed into programmatic consultations.

Response: The Services' existing regulations and practice allow for this approach and, in many situations, an applicant's compliance with ESA section 7(a)(2) requirements through an existing incidental take permit under an ESA section 10 HCP can be achieved. In these cases, Federal agencies can meet their separate section 7(a)(2) responsibilities using a simple expedited process. Thus, no regulatory changes are necessary.

Comment 3: One commenter suggested that the Services align ESA terms similar to terminology in the National Environmental Policy Act (NEPA), *e.g.,* ''mitigation,'' and that we use consistent language in regulations and not switch between the terms ''effects'' and ''impacts.''

Response: The Services decline to undertake the action recommended by this commenter. ESA section 7(a)(2) and its implementing regulations include specific terms of art that are not interchangeable with terms used in other statutory contexts such as NEPA. See above in the ''environmental baseline'' section for discussion of the Services' use of the terms ''effects'' and ''impacts.''

Comment 4: A couple of commenters stated the ESA Compensatory Mitigation Policy was issued without opportunity for public notice and comment.

Response: The FWS ESA Compensatory Mitigation Policy (Appendix 1, 501 FW 3 *https://www.fws.gov/policy-library/a1501fw3*) provides internal, non-binding guidance and does not establish legally binding rules. Because the policy is guidance rather than a rule, there are no requirements for public review and comment. Nonetheless, the FWS solicited public comment during three separate public comment periods related to the 2016 FWS mitigation policies. The initial public comment periods solicited input on the proposed revisions to the Mitigation Policy (81 FR 12380, March 8, 2016), and on the draft

ESA Compensatory Mitigation Policy (81 FR 61031, September 2, 2016). The FWS later requested additional public comment on the mitigation planning goal within both mitigation policies that had already been finalized (82 FR 51382, November 6, 2017). The documents, comments, and process related to prior revisions may be viewed within docket number FWS–HQ–ES–2015–0126 (mitigation) and docket number FWS–HQ–ES–2015–0165 (compensatory mitigation) on *https://www.regulations.gov.* The final ESA Compensatory Mitigation Policy is substantively similar to the 2016 policy and reflects input from those previous public-comment opportunities.

Comments on Determinations

Comment 1: One commenter asserted the need to complete intra-service consultation pursuant to section 7 of the Act on the issuance of the final regulations.

Response: We have addressed this issue in our Required Determinations section of the preamble to this final rule.

Comment 2: Several commenters requested additional economic analyses pursuant to Executive Order (E.O.) 12866 and related E.O.s. Some commenters suggested that the Services characterize the rulemaking as a ''significant regulatory action'' and that we must include an economic analysis as specified in Office of Management and Budget (OMB) Circular A–4. Several commenters expressed concern with potential costs associated with the RPM revisions.

Response: Although OMB determined that the proposed revisions to 50 CFR part 402 were a significant regulatory action pursuant to E.O. 12866, OMB agreed with the Services' assessment that the expected effects of the proposed rule did not fall within the scope of E.O. 12866 section 3(f)(1) and did not warrant an analysis as specified in OMB Circular A–4. We do not anticipate the revisions to result in any substantial change in our determinations as to whether proposed actions are likely to jeopardize listed species or result in the destruction or adverse modification of critical habitat. None of these changes are expected to result in delays to completing consultations in a timely manner or within the statutory or regulatory timeframes. And, although offsetting measures as RPMs can be associated with costs, those measures must be constrained by the statutory and regulatory requirements of RPMs, as we have noted in response to previous comments. It is worth noting that any economic analysis of the revisions to RPMs would be limited by substantial uncertainty about how many formal consultations will include offsetting measures as RPMs due to the tremendous variation in Federal actions subject to formal consultation, the specific impacts from these actions, and the affected species that may be analyzed. Although we cannot predict the costs of the RPM proposal due to these variable factors associated with formal consultations, any costs would be constrained by the statutory and regulatory requirements of RPMs as described above and in the proposed rule. Thus, because consultations under section 7(a)(2) are so highly fact-specific, it is also not possible to specify future benefits or costs stemming from this rulemaking.

Comment 3: Several commenters believed the Services' findings under the Regulatory Flexibility Act (RFA) and consideration of responsibilities under Executive Order (E.O.) 13132 (Federalism) and E.O. 13211 (Effects on the Energy Supply) were insufficient or incorrect. Commenters claimed that modifying existing consultation requirements will likely result in increased compliance costs and delays for projects involving small entities. The commenters also disagreed with our finding for E.O. 12630 (Takings) that the proposed rule would not have significant takings implications and that a takings implication assessment is not warranted. They urged us to conduct additional assessments before finalizing the rule.

Response: Regarding all required determinations for the rulemaking, all the revisions provide transparency and clarity to the consultation process under section 7(a)(2) of the Act and align the regulations with the plain language of the statute. As a result, we do not anticipate any substantial change in our determinations as to whether proposed actions are likely to jeopardize listed species or result in the destruction or adverse modification of critical habitat. Regarding the revisions to RPMs, most consultations under section 7(a)(2) will not be affected since most consultations are completed informally, and this change would apply only to formal consultations that require an ITS containing RPMs. Even among formal consultations that require an ITS containing RPMs, some of these consultations will be able to address impacts of incidental take through measures that avoid or reduce incidental take within the action area, and the change would not apply to those consultations.

Regarding the RFA and E.O. 13211, this final rule which contains revisions that provide transparency, clarity, and more closely comport with the text of the ESA, will not have a significant economic impact on a substantial number of small entities or any other entities and is unlikely to cause any adverse effects on energy supply, distribution, or use (including a shortfall in supply, price increases, and increased use of foreign supplies). An analysis of small entity impacts is required when a rule directly affects small entities. However, Federal agencies are the only entities directly affected by this rule, and they are not considered to be small entities under SBA's size standards. No other entities will be directly affected by this rulemaking action. While some commenters suggested that the rule may impact small entities indirectly as applicants to Federal actions subject to ESA section 7(a)(2), we are unaware of any significant economic effect on a substantial number of small entities. Although we received comments raising generalized concerns about alleged potential effects on small entities, none of these comments described direct, concrete economic effects on small entities, much less ''significant'' economic effects on a ''substantial'' number of small entities.

Regarding E.O. 13132, ''Policies that have federalism implications,'' that Executive Order includes federalism implications from regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. This rulemaking has no such federalism implications. Federal agencies are the only entities that are directly affected by this rule, as a Federal nexus is necessary for requiring consultation under section 7(a)(2) of the ESA. In addition, as stated for E.O. 13132 in the Required Determinations section of this preamble, this rule pertains only to improving and clarifying the interagency consultation processes under the ESA and would not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Regarding E.O. 12630, as discussed in the proposed rule, this rulemaking will not directly affect private property, nor will it cause a physical or regulatory taking. It will not result in a physical taking because it will not effectively compel a property owner to suffer a physical invasion of property. Further,

the rulemaking will not result in a regulatory taking because it will not deny all economically beneficial or productive use of the land or aquatic resources. This rule will substantially advance a legitimate government interest (conservation and recovery of endangered species and threatened species) and will not present a barrier to all reasonable and expected beneficial use of private property.

Required Determinations

Regulatory Planning and Review—Executive Orders 12866, 13563, and 14094

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) will review all significant rules. OIRA has determined that this rule is significant.

Executive Order 14094 amends E.O. 12866 and reaffirms the principles of E.O. 12866 and E.O 13563 and states that regulatory analysis should facilitate agency efforts to develop regulations that serve the public interest, advance statutory objectives, and be consistent with E.O. 12866, E.O. 13563, and the Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review). Regulatory analysis, as practicable and appropriate, shall recognize distributive impacts and equity, to the extent permitted by law. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this final rule in a manner consistent with these requirements.

Revisions to 50 CFR part 402. Specifically, the Services are revising the implementing regulations at: (1) § 402.02, definitions; (2) § 402.16, reinitiation of consultation; (3) § 402.17, other provisions; and (4) § 402.14(i)(1), formal consultation. The preamble to the proposed rule explains in detail why we anticipate that the regulatory changes we are proposing will improve the implementation of the Act (88 FR 40753, June 22, 2023).

When we made changes to §§ 402.02, 402.16, and 402.17 in 2019, we compiled historical data for a variety of metrics associated with the consultation process in an effort to describe for OMB and the public the effects of those regulations (on *https://www.regulations.gov,* see Supporting Document No. FWS–HQ–ES–2018–0009–64309 of Docket No. FWS–HQ–ES–2018–0009; Docket No. 180207140–8140–01). We presented various metrics related to the regulation revisions, as well as historical data supporting the metrics.

For the 2019 regulations, we concluded that because those revisions served to clarify rather than alter the standards for consultation under section 7(a)(2) of the Act, the 2019 regulation revisions were substantially unlikely to affect our determinations as to whether proposed Federal actions are likely to jeopardize listed species or result in the destruction or adverse modification of critical habitat.

As with the 2019 regulations, the revisions in this rule, as described above, are intended to provide transparency and clarity and align more closely with the statute. As a result, we do not anticipate any substantial change in our determinations as to whether proposed actions are likely to jeopardize listed species or result in the destruction or adverse modification of critical habitat.

Similarly, although the revisions to the regulatory provisions relating to RPMs in this final rule are amendments that were not considered in the 2019 rulemaking, this final rule will align the regulations with the plain language of the statute. These changes will not affect most consultations under section 7(a)(2) of the Act because most consultations are completed informally, and this regulation will apply only to formal consultations that require an ITS containing RPMs. Even among formal consultations that require an ITS containing RPMs, some of these consultations will be able to address impacts of incidental take through measures that avoid or reduce incidental take within the action area, and offsets would be considered only if measures that avoid or reduce incidental take cannot feasibly minimize the impacts of incidental take caused by the proposed action. As explained in the preamble language above, the use of offsetting measures in RPMs will not be required in every consultation. As with all RPMs, these offsetting measures must be commensurate with the scale of the impact, subject to the existing ''minor change rule,'' be reasonable and prudent, and be necessary or appropriate to minimize the impact of the incidental taking on the species.

Lastly, several different action agencies in various locations throughout the country readily include offsetting measures as part of their project descriptions. This practice of including offsets as part of the proposed action being evaluated in a consultation is not uncommon. The Services may find that offsets included in the proposed action adequately minimize impacts of incidental take, thus obviating the need to specify additional offsets as RPMs. Examples of these types of consultations that incorporate offsetting measures into the proposed action include programmatic consultations, certain consultations regarding transportation projects, and activities authorized by the U.S. Army Corps of Engineers under Section 404 of the Clean Water Act (33 U.S.C. 1344).

It is not possible to know how many formal consultations will include offsetting measures as RPMs due to the tremendous variation in Federal actions subject to formal consultation, the specific impacts from these actions, and the affected species that may be analyzed. Although we cannot predict the costs of the RPM regulation due to these variable factors associated with formal consultations, any costs would be constrained by the statutory and regulatory requirements that RPMs are ''reasonable and prudent,'' commensurate with the residual impacts of incidental take caused by the proposed action, and subject to the ''minor change rule.''

Similarly, while we cannot quantify the benefits from this rule, some of the benefits include further minimization of the impacts of incidental take caused by the proposed action, which, in turn, further mitigates some of the environmental ''costs'' associated with that action. In allowing for residual impacts to be addressed, the rule may also reduce the accumulation of adverse impacts to the species that is often referred to as ''death by a thousand cuts.'' Sources of offsetting measures, such as conservation banks and in-lieu fee programs, have proven in other analogous contexts to be a cost-effective means of mitigating environmental impacts and may have the potential to enhance mitigative measures directed at the loss of endangered and threatened species when they are applied strategically. See, *e.g.,* U.S. Fish and Wildlife Service Mitigation Policy and Endangered Species Act Compensatory Mitigation Policy, Appendix 1, 501 FW 3 (May 15, 2023) or NOAA Mitigation Policy for Trust Resources, NOA 216–123 (July 22, 2022).

The regulatory changes in this rule provide transparency, clarity, and more closely comport with the text of the ESA. We, therefore, do not anticipate any material effects such that the rule would have an annual effect that would reach or exceed $200 million or would 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, territorial, or Tribal governments or communities.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996; 5 U.S.C. 601 *et seq.*), whenever a Federal agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare, and make available for public comment, a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions) directly affected by the rule. However, no regulatory flexibility analysis is required if the head of an agency, or that person's designee, certifies that the rule will not have a significant economic impact on a substantial number of small entities. SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities. We certified at the proposed rule stage that this rule would not have a significant economic impact on a substantial number of small entities (88 FR 40761). We received no information that changes the factual basis of this certification.

This rulemaking revises and clarifies existing requirements for Federal agencies, including the Services, under section 7 of the ESA. Federal agencies are the only entities directly affected by this rule, and they are not considered to be small entities under SBA's size standards. No other entities would be directly affected by this rulemaking action. While some commenters suggested that the rule may impact small entities indirectly as applicants to Federal actions subject to ESA section 7(a)(2), we are unaware of any significant economic effect on a substantial number of small entities. Although we received comments raising generalized concerns about alleged potential effects on small entities, none of these comments described direct, concrete economic effects on small entities, much less ''significant'' economic effects on a ''substantial'' number of small entities.

This rulemaking applies to determining whether a Federal agency has ensured, in consultation with the Services, that any action it would authorize, fund, or carry out is not likely to jeopardize listed species or result in the destruction or adverse modification of critical habitat. This rulemaking will not result in any additional change in our determination as to whether proposed actions are likely to jeopardize listed species or result in the destruction or adverse modification of critical habitat. This rulemaking serves to provide clarity to the standards with which we will evaluate agency actions pursuant to section 7 of the ESA.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*):

(a) On the basis of information presented under *Regulatory Flexibility Act* above, this rule will not ''significantly or uniquely'' affect small governments. We have determined and certify pursuant to the Unfunded Mandates Reform Act, 2 U.S.C. 1502, that this rule will not impose a cost of $100 million or more in any given year on local or State governments or private entities. A small government agency plan is not required. As explained above, small governments will not be affected because the rule will not place additional requirements on any city, county, or other local municipalities.

(b) This rule will not produce a Federal mandate on State, local, or Tribal governments or the private sector of $100 million or greater in any year; that is, this rule is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act. This rule will impose no obligations on State, local, or Tribal governments.

Takings (E.O. 12630)

In accordance with E.O. 12630, this rule will not have significant takings implications. This rule will not directly affect private property, nor will it cause a physical or regulatory taking. It will not result in a physical taking because it will not effectively compel a property owner to suffer a physical invasion of property. Further, the rule will not result in a regulatory taking because it will not deny all economically beneficial or productive use of the land or aquatic resources, and it will substantially advance a legitimate government interest (conservation and recovery of endangered species and threatened species) and will not present a barrier to all reasonable and expected beneficial use of private property.

Federalism (E.O. 13132)

In accordance with E.O. 13132, we have considered whether this rule will have significant federalism effects and have determined that a federalism summary impact statement is not required. This rule pertains only to improving and clarifying the interagency consultation processes under the ESA and will not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Civil Justice Reform (E.O. 12988)

This rule does not unduly burden the judicial system and meets the applicable standards provided in sections 3(a) and 3(b)(2) of E.O. 12988. This rule revises the Service's regulations for protecting species pursuant to the Act.

Government-to-Government Relationship With Tribes

In accordance with E.O. 13175, ''Consultation and Coordination with Indian Tribal Governments,'' and the Department of the Interior's manual at 512 DM 2, we have considered possible effects of this rule on federally recognized Indian Tribes and Alaska Native Corporations. We held three informational webinars for federally recognized Tribes in January 2023, before the June 22, 2023, proposed rule published, to provide a general overview of, and information on how to provide input on, a series of rulemakings related to implementation of the Act that the Services were developing, including the June 22, 2023, proposed rule to revise our regulations at 50 CFR part 402. In July 2023, we also held six informational webinars after the proposed rule published, to provide additional information to interested parties, including Tribes, regarding the proposed regulations. Over 500 attendees, including representatives from federally recognized Tribes and Alaska Native Corporations, participated in these sessions, and we addressed questions from the participants as part of the sessions. We received written comments from Tribal organizations; however, we did not receive any requests for coordination or government-to-government consultation from any federally recognized Tribes.

This rule is general in nature and does not directly affect any specific Tribal lands, treaty rights, or Tribal trust resources. Therefore, we conclude that this rule does not have Tribal implications under section 1(a) of E.O. 13175. Thus, formal government-to-government consultation is not required by E.O. 13175 and related DOI policies. This rule revises regulations for protecting endangered and threatened species pursuant to the Act. These regulations will 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.

We will continue to collaborate with Tribes and Alaska Native Corporations on issues related to federally listed species and their habitats and work with them as we implement the provisions of the Act. See Secretaries' Order 3206 (''American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act,'' June 5, 1997) and Secretaries' Order 3225 (''Endangered Species Act and Subsistence Uses in Alaska (Supplement to Secretarial Order 3206),'' January 19, 2001).

Paperwork Reduction Act

This rule does not contain any new collection of information that requires approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act

In the proposed rule we invited the public to comment on whether and how the regulation may have a significant impact on the human environment, including any effects identified as extraordinary circumstances at 43 CFR 46.25 or fall within one of the categorical exclusions for actions that have no individual or cumulative effect on the quality of the human environment. After considering the comments received, the Services analyzed this rule in accordance with the criteria of the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), the Council on Environmental Quality NEPA regulations (40 CFR parts 1500–1508), the Department of the Interior (DOI) NEPA regulations (43 CFR part 46), the DOI 516 Departmental Manual Chapters 1–4 and 8, and the National Oceanic and Atmospheric Administration (NOAA) Policy and Procedures for Compliance with the National Environmental Policy Act and Related Authorities (NOAA Administrative Order (NAO) 216–6A and Companion Manual for NAO 216–6A. This analysis was undertaken in an abundance of caution only, as we maintain that one or more categorical exclusions apply to this rule. Documentation of our compliance under NEPA is available online at *https://www.regulations.gov* at Docket No. FWS–HQ–ES–2021–0104.

Endangered Species Act

In developing this final rule, the Services are acting in their unique statutory role as administrators of the Act and are engaged in a legal exercise of interpreting the standards of the Act. The Services' promulgation of interpretive rules that govern their implementation of the Act is not an action that is in itself subject to the Act's provisions, including section 7(a)(2). The Services have a historical practice of issuing their general implementing regulations under the ESA without undertaking section 7 consultation. Given the plain language, structure, and purposes of the ESA, we find that Congress never intended to place a consultation obligation on the Services' promulgation of implementing regulations under the Act. In contrast to actions in which we have acted principally as an ''action agency'' in implementing the Act to propose or take a specific action (*e.g.,* issuance of section 10 permits and actions under statutory authorities other than the ESA), with this document, the Services are carrying out an action that is at the very core of their unique statutory role as administrators—promulgating general implementing regulations or revisions to those regulations that interpret the terms and standards of the statute.

Energy Supply, Distribution or Use (E.O. 13211)

Executive Order 13211 requires agencies to prepare statements of energy effects when undertaking certain actions. The revised regulations are not expected to affect energy supplies, distribution, and use. Therefore, this action is not a significant energy action, and no statement of energy effects is required.

Authority

We issue this final rule under the authority of the Endangered Species Act, as amended (16 U.S.C. 1531 *et seq.*).

List of Subjects in 50 CFR Part 402

Endangered and threatened species.

Regulation Promulgation

Accordingly, we amend part 402, subchapter A of chapter IV, title 50 of the Code of Federal Regulations, as set forth below:

PART 402—INTERAGENCY COOPERATION—ENDANGERED SPECIES ACT OF 1973, AS AMENDED

■ 1. The authority citation for part 402 continues to read as follows:

Authority: 16 U.S.C. 1531 *et seq.*

Subpart A—General

■ 2. Amend § 402.02 by revising the definitions of ''Effects of the action'', ''Environmental baseline'', and ''Reasonable and prudent measures'' to read as follows:

§ 402.02 Definitions.

* * * * *

Effects of the action are all consequences to listed species or critical habitat that are caused by the proposed action, including the consequences of other activities that are caused by the proposed action but that are not part of the action. A consequence is caused by the proposed action if it would not occur but for the proposed action and it is reasonably certain to occur. Effects of the action may occur later in time and may include consequences occurring outside the immediate area involved in the action.

Environmental baseline refers to the condition of the listed species or its designated critical habitat in the action area, without the consequences to the listed species or designated critical habitat caused by the proposed action. The environmental baseline includes the past and present impacts of all Federal, State, or private actions and other human activities in the action area, the anticipated impacts of all proposed Federal projects in the action area that have already undergone formal or early section 7 consultation, and the impact of State or private actions which are contemporaneous with the consultation in process. The impacts to listed species or designated critical habitat from Federal agency activities or existing Federal agency facilities that are not within the agency's discretion to modify are part of the environmental baseline.

* * * * *

Reasonable and prudent measures refer to those actions the Director considers necessary or appropriate to minimize the impact of the incidental take on the species.

* * * * *

Subpart B—Consultation Procedures

■ 3. Amend § 402.14 by revising paragraph (i) to read as follows:

§ 402.14 Formal consultation.

* * * * *

(i) *Incidental take.* (1) In those cases where the Service concludes that an action (or the implementation of any reasonable and prudent alternatives) and the resultant incidental take of listed species will not violate section 7(a)(2), and, in the case of marine

mammals, where the taking is authorized pursuant to section 101(a)(5) of the Marine Mammal Protection Act of 1972, the Service will provide with the biological opinion a statement concerning incidental take that:

(i) Specifies the impact of incidental taking as the amount or extent of such taking. A surrogate (*e.g.,* similarly affected species or habitat or ecological conditions) may be used to express the amount or extent of anticipated take, provided that the biological opinion or incidental take statement: Describes the causal link between the surrogate and take of the listed species, explains why it is not practical to express the amount or extent of anticipated take or to monitor take-related impacts in terms of individuals of the listed species, and sets a clear standard for determining when the level of anticipated take has been exceeded;

(ii) Specifies those reasonable and prudent measures that the Director considers necessary or appropriate to minimize such impact of incidental taking on the species;

(iii) In the case of marine mammals, specifies those measures that are necessary to comply with section 101(a)(5) of the Marine Mammal Protection Act of 1972 and applicable regulations with regard to such taking;

(iv) Sets forth the terms and conditions (including, but not limited to, reporting requirements) that must be complied with by the Federal agency or any applicant to implement the measures specified under paragraphs (i)(1)(ii) and (iii) of this section; and

(v) Specifies the procedures to be used to handle or dispose of any individuals of a species actually taken.

(2) Reasonable and prudent measures, along with the terms and conditions that implement them, cannot alter the basic design, location, scope, duration, or timing of the action, may involve only minor changes, and may include measures implemented inside or outside of the action area that avoid, reduce, or offset the impact of incidental take.

(3) Priority should be given to developing reasonable and prudent measures and terms and conditions that avoid or reduce the amount or extent of incidental taking anticipated to occur within the action area. To the extent it is anticipated that the action will cause incidental take that cannot feasibly be avoided or reduced in the action area, the Services may set forth additional reasonable and prudent measures and terms and conditions that serve to minimize the impact of such taking on the species inside or outside the action area.

(4) In order to monitor the impacts of incidental take, the Federal agency or any applicant must report the progress of the action and its impact on the species to the Service as specified in the incidental take statement. The reporting requirements will be established in accordance with 50 CFR 13.45 and 18.27 for FWS and 50 CFR 216.105 and 222.301(h) for NMFS.

(5) If during the course of the action the amount or extent of incidental taking, as specified under paragraph (i)(1)(i) of this section, is exceeded, the Federal agency must reinitiate consultation immediately.

(6) Any taking that is subject to a statement as specified in paragraph (i)(1) of this section and that is in compliance with the terms and conditions of that statement is not a prohibited taking under the Act, and no other authorization or permit under the Act is required.

(7) For a framework programmatic action, an incidental take statement is not required at the programmatic level; any incidental take resulting from any action subsequently authorized, funded, or carried out under the program will be addressed in subsequent section 7 consultation, as appropriate. For a mixed programmatic action, an incidental take statement is required at the programmatic level only for those program actions that are reasonably certain to cause take and are not subject to further section 7 consultation.

* * * * *

■ 4. Amend § 402.16 by revising the introductory text of paragraph (a) to read as follows:

§ 402.16 Reinitiation of consultation.

(a) Reinitiation of consultation is required and shall be requested by the Federal agency, where discretionary Federal involvement or control over the action has been retained or is authorized by law and:

* * * * *

§ 402.17 [Removed]

■ 5. Remove § 402.17.

Shannon A. Estenoz,

Assistant Secretary for Fish and Wildlife and Parks, Department of the Interior.

Richard Spinrad,

Under Secretary of Commerce for Oceans and Atmosphere, NOAA Administrator, National Oceanic and Atmospheric Administration.

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Part V

Department of the Interior

Fish and Wildlife Service

Department of Commerce

National Oceanic and Atmospheric Administration
50 CFR Part 424

Endangered and Threatened Wildlife and Plants; Listing Endangered and Threatened Species and Designating Critical Habitat; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 424

[Docket No. FWS–HQ–ES–2021–0107, FXES1111090FEDR–245–FF09E23000; Docket No. 240325–0088]

RIN 1018–BF95; 0648–BK47

Endangered and Threatened Wildlife and Plants; Listing Endangered and Threatened Species and Designating Critical Habitat

AGENCY: U.S. Fish and Wildlife Service, Interior; National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Commerce.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS; collectively, the ''Services''), finalize revisions to portions of our regulations that implement section 4 of the Endangered Species Act of 1973, as amended. The revisions to the regulations clarify, interpret, and implement portions of the Act concerning the procedures and criteria used for listing, reclassifying, and delisting species on the Lists of Endangered and Threatened Wildlife and Plants (Lists) and designating critical habitat.

DATES: This final rule is effective May 6, 2024.

ADDRESSES: Public comments and materials received, as well as supporting documentation used in the preparation of this final rule, are available online at *https://www.regulations.gov* in docket number FWS–HQ–ES–2021–0107.

FOR FURTHER INFORMATION CONTACT: Carey Galst, U.S. Fish and Wildlife Service, Division of Ecological Services, Branch of Listing Policy and Support Chief, 5275 Leesburg Pike, Falls Church, VA 22041–3803, telephone 703–358–1954; or Angela Somma, National Marine Fisheries Service, Office of Protected Resources, Endangered Species Division Chief, 1315 East-West Highway, Silver Spring, MD 20910, telephone 301–427–8403. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Background

The Secretaries of the Interior and Commerce (''Secretaries'' or ''Secretary'') share responsibilities for implementing most of the provisions of the Endangered Species Act of 1973, as amended (''ESA'' or ''the Act,'' 16 U.S.C. 1531 *et seq.*), and authority to administer the Act has been delegated by the respective Secretaries to the Director of FWS and the Assistant Administrator for NMFS. Together, the Services have promulgated regulations that interpret aspects of the listing and critical habitat designation provisions of section 4 of the Act. These joint regulations, which are codified in the Code of Federal Regulations (CFR) at 50 CFR part 424, were most recently revised in 2019 (84 FR 45020, August 27, 2019; ''the 2019 rule'' or ''the 2019 regulations''). Those revised regulations became effective on September 26, 2019.

Executive Order 13990 (E.O. 13990), entitled ''Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis,'' was issued on January 20, 2021. E.O. 13990 directed all departments and agencies to immediately review agency actions taken between January 20, 2017, and January 20, 2021, and, as appropriate and consistent with applicable law, consider suspending, revising, or rescinding agency actions that conflict with important national objectives, including promoting and protecting our public health and the environment, and to immediately commence work to confront the climate crisis. A Fact Sheet that accompanied E.O. 13990 provided a non-exhaustive list of particular regulations requiring such a review and included the 2019 rule (see *https://www.whitehouse.gov/briefing-room/statementsreleases/2021/01/20/fact-sheet-list-of-agency-actions-for-review/*). In response to E.O. 13990 and litigation that ended with a court remand of the 2019 rule, the Services reviewed the 2019 rule and, on June 22, 2023, published a proposed rule to revise portions of the implementing regulations at 50 CFR part 424 (88 FR 40764) that had previously been revised by the 2019 rule. We solicited public comments on the June 22, 2023, proposed rule for 60 days, ending August 21, 2023.

Section 2 of the Act states that the purposes of the Act include providing a means to conserve the ecosystems upon which endangered and threatened species depend, developing a program for the conservation of listed species, and achieving the purposes of certain treaties and conventions (16 U.S.C. 1531(b)). Section 2 of the Act also makes explicit that it is the policy of Congress that all Federal agencies and departments seek to conserve threatened and endangered species and use their authorities to further the purposes of the Act (16 U.S.C. 1531(c)).

To determine whether listing a species is warranted, the Act requires that the Services conduct a review of the status of the species and consider any efforts being made by any State or foreign nation (or subdivision thereof) to protect the species. The Act also requires that determinations of whether a species meets the definition of an endangered or threatened species be based solely on the best scientific and commercial data available (16 U.S.C. 1533(b)(1)(A)). Once species are listed, section 4(c)(2) of the Act requires us to conduct a review at least once every 5 years to determine whether the listed species should be removed from the Lists or changed in status, and section 4(f) of the Act requires that we develop and implement recovery plans for the conservation and survival of the listed species (unless a finding is made that such a plan would not promote the conservation of the species) (16 U.S.C. 1533(c)(2) and (f)). To the maximum extent practicable, recovery plans are required to provide certain elements, including objective, measurable criteria, which when met, would result in a determination that the species should be removed from the list.

Section 4(a)(3)(A) of the Act requires the Services to designate critical habitat concurrent with the listing rule to the maximum extent prudent and determinable, or issue a final critical habitat rule within 1 year following a final listing rule if critical habitat was not initially determinable. Critical habitat is defined in section 3 of the Act as: (1) the specific areas within the geographical area occupied by the species at the time it is listed on which are found those physical or biological features that are essential to the conservation of the species and that may require special management considerations or protection; and (2) specific areas outside the geographic area occupied by the species at the time it is listed upon a determination by the Secretary that such areas are essential for the conservation of the species (16 U.S.C. 1532(5)). The two parts of this definition for critical habitat depend on whether the species occupies an area or does not occupy an area at the time of

listing. For simplicity, throughout this document we will refer to the former type of area as ''occupied'' critical habitat and the latter type as ''unoccupied'' critical habitat.

In passing the Act, Congress viewed habitat loss as a significant factor contributing to species endangerment, and the ''present or threatened destruction, modification, or curtailment'' of a species' habitat or range is specifically enumerated in section 4(a)(1) of the Act as the first of the factors that may underlie a determination that a species meets the definition of an endangered or threatened species. The designation of critical habitat is a regulatory tool designed to further the conservation of a listed species, *i.e.,* to help bring the endangered or threatened species to the point at which protections under the Act are no longer necessary. More broadly, designation of critical habitat also serves as a tool for meeting one of the Act's stated purposes: Providing a means for conserving the ecosystems upon which endangered and threatened species depend. Once critical habitat is designated, Federal agencies must ensure that any actions they authorize, fund, or carry out are not likely to result in destruction or adverse modification of the critical habitat (16 U.S.C. 1536(a)(2)).

In this final rule, we summarize and discuss the comments received in response to the proposed rule (88 FR 40764, June 22, 2023), and outline changes from the proposed rule based on our consideration of those comments and in light of the objectives of this rulemaking process to address concerns we had identified in the 2019 rule, the policies expressed in E.O. 13990, and our experience with implementing the Act. In the event any provision is invalidated or held to be impermissible as a result of a legal challenge, ''the remainder of the regulation could function sensibly without the stricken provision.'' *Belmont Mun. Light Dep't* v. *FERC,* 38 F.4th 173, 187 (D.C. Cir. 2022) (quoting *MD/DC/DE Broad. Ass'n* v. *FCC,* 236 F.3d 13, 22 (D.C. Cir. 2001)). Because each of the provisions stand on their own, the Services view each of the provisions as operating independently from the other provisions. Thus, should a reviewing court invalidate any particular provision(s) of this rulemaking, the remaining provisions would still allow the Services to classify species and designate their critical habitat. Specifically, these distinct provisions include: (1) economic and other impacts; (2) foreseeable future; (3) factors considered in delisting species; (4) not prudent determinations; and (5) designation of unoccupied critical habitat. To illustrate this with one example, in the event that a reviewing Court would find that the revisions to the foreseeable future regulatory language is invalid, that finding would not affect the revisions to the factors considered in the designation of unoccupied critical habitat. Therefore, in the event that any portion of this final rule is held to be invalid or impermissible, the Services intend that the remaining aspects of the regulatory provisions be severable.

In finalizing the specific changes to the ESA implementing regulations in this document, the Services are establishing prospective standards only. These regulations will apply to classification and critical habitat rules finalized after the effective date of this rule and will not apply retroactively to classification and critical habitat rules finalized prior to the effective date of this rule. (For the effective date of this rule, see **DATES**, above.) Nothing in these revisions to the regulations is intended to require that any prior final listing, delisting, or reclassification determinations or previously completed critical habitat designations be reevaluated on the basis of these final regulations.

This final rule is one of three final rules publishing in today's **Federal Register** that make changes to the regulations that implement the ESA. Two of these final rules, including this one, are joint between the Services, and one final rule is specific to FWS.

Changes From the Proposed Rule

In this section, we discuss changes between the proposed regulatory text and the regulatory text that we are finalizing in this document. We have modified the text we proposed for two sections of the regulations—the foreseeable future regulation in 50 CFR 424.11(d) and the delisting regulations in 50 CFR 424.11(e). We are not making modifications to any other sections of the regulations in 50 CFR part 424 that were addressed in the 2023 proposed rule (88 FR 40764, June 22, 2023); we are finalizing those sections as proposed.

Foreseeable Future

The ESA defines ''threatened species'' as ''any species that is likely to become an endangered species in the foreseeable future'' (16 U.S.C. 1532(2)). As part of the 2019 rule, the Services issued a regulation explaining how to apply the ''foreseeable future'' language (50 CFR 424.11(d)). In the proposed rule, we proposed to revise the second sentence of the foreseeable future regulation in 50 CFR 424.11(d) to state, ''The term foreseeable future extends as far into the future as the Services can reasonably rely on information about the threats to the species and the species' responses to those threats.'' As explained below, we have modified that sentence so that it now states, ''The foreseeable future extends as far into the future as the Services can make reasonably reliable predictions about the threats to the species and the species' responses to those threats.''

The Services received numerous comments that the proposed revisions were vague and unclear, would result in foreseeable-future timeframes that were limitless, or lowered the standard needed to list species. Some commenters requested that we rescind the regulation or rely on the 2009 Memorandum Opinion on the foreseeable future from the Department of the Interior, Office of the Solicitor (M–37021, January 16, 2009; ''M-Opinion'', available online at *https://www.doi.gov/sites/doi.opengov.ibmcloud.com/files/uploads/M-37021.pdf*). Other commenters stated that the Services should retain this regulation in some form, as the M-Opinion does not have the force of law. In response to these comments and upon further consideration, we decided not to rescind the regulation but to, instead, modify it for clarity.

We are not rescinding the 2019 regulation because including a foreseeable future framework in our regulations establishes binding standards for the Services to apply and promotes transparency to the public by setting out our understanding of the foreseeable future in the CFR, where it can be read in context with other regulatory provisions implementing section 4. We are, however, revising the regulation because the language from the 2019 regulation (*i.e.,* ''reasonably determine that both the future threats and the species' responses to those threats are likely'') created confusion. The 2019 regulation seemed to suggest that the Services had adopted a novel requirement to determine the foreseeable future by first determining the likely effects of threats on the species. With this rule, the Services clarify that the foreseeable future regulation does not function as an independent substantive standard in the context of a listing decision. Rather, the foreseeable future articulates how the Services determine the appropriate timeframe over which to evaluate the best scientific and commercial data available when determining whether the species meets the substantive standard

set out in the Act's definition of a threatened species.

In response to public comments on the proposed rule, we have further revised the second sentence of the regulation to state that the foreseeable future extends as far into the future as the Services can make reasonably reliable predictions about the threats to the species and the species' responses to those threats. Specifically, we made two changes to the second sentence. First, we removed the word ''term'' from the second sentence because it is unnecessary, and the sentence is clearer without this word. Second, we removed the phrase ''reasonably rely on information'' and replaced it with ''make reasonably reliable predictions.'' In light of the public comments received, we determined that the phrase ''reasonably rely on information'' in the proposed rule did not provide the clarity that we intended with respect to explaining how far into the future the Services can use information to assess future threats and species' responses to those threats.

Many of the commenters referred to the M-Opinion as being preferable because it better explains the role of the ''foreseeable future'' phrase in the Act and is more understandable than the regulatory text we proposed. The M-Opinion explains, based on contemporaneous dictionary definitions of ''foreseeable'' and the statutory context in which the term appears, that what constitutes the foreseeable future for a particular listing determination must be rooted in the best available data that allow predictions into the future, and that the foreseeable future extends only so far as those predictions are reliable. Because the M-Opinion provided a well-reasoned interpretation of this statutory term, following a thorough analysis of the text and structure of the ESA and its legislative history, it has guided the Services' longstanding practice. The comments we received confirmed that the interpretation we had been applying, as guided by the M-Opinion, is well understood and accepted. Therefore, we have now rephrased the regulatory text to better reflect that legal analysis and our longstanding practice by stating that the foreseeable future extends as far into the future as the Services can ''make reasonably reliable predictions.''

As noted above, the term ''foreseeable future'' is a term contained in the statutory definition of ''threatened species'' (16 U.S.C. 1532(20)), yet Congress did not define ''foreseeable future'' in the Act. Since 2009, the Services have relied on the M-Opinion for internal guidance in interpreting and applying this term. As part of our assessment of a species' status, we evaluate how threats may already have affected the species by considering available data regarding abundance and population trends, and we evaluate how threats may affect the species in the future. When conducting this analysis, we must review the degree of certainty and foreseeability concerning each of the threats to the species and the species' responses to those threats. We must assess the nature of the best scientific and commercial data available concerning each threat and the degree to which the data allow us to make reliable predictions. Predictions about the occurrence of an event or a response in the future are inherently uncertain. The M-Opinion explores ordinary definitions of the word ''foreseeable'' and refers to the event as ''being such as may reasonably be anticipated'' or ''lying within the range for which forecasts are possible'' (M-Opinion, at 8 (emphasis removed)). It goes on to explain further that a ''forecast'' is defined as a prophecy, estimate, or prediction of a future happening or condition, and the verb ''forecast'' is defined as to anticipate, calculate, or predict some future event or condition as a result of rational study and analysis of pertinent data (*id.*). The M-Opinion states that we look not only at the foreseeability of threats, but also at the foreseeability of the impact of the threats on the species. In some cases, a species' responses to a foreseeable threat will manifest immediately; in other cases, it may be multiple generations before a foreseeable threat's effect on the species can be observed. But in each case, we must be able to make reliable predictions about the future impact to the species from the foreseeable threat. The further into the future that we assess threats to a species or a species' responses to threats, the greater the burden on the Services to explain how we can conclude that those future threats or responses remain foreseeable—that is, that our assessments of them are based on reasonably reliable predictions out to that point in the future. In making these predictions, we must avoid speculation and presumption. Thus, for a particular species, we may conclude, based on the extent or nature of the best data available, that a trend has only a certain degree or period of reliability, and that to extrapolate the trend beyond that point would constitute speculation. Therefore, following our consideration of the public comments, we have revised the second sentence of the framework to state that the ''foreseeable future'' extends as far into the future as the Services can make reasonably reliable predictions about the threats to the species and the species' responses to those threats. The remainder of the framework is unchanged.

The M-Opinion, which we have relied on since 2009, includes a detailed analysis of the Act, legislative history, and case law and, based on that analysis, develops a set of considerations for determining the extent of the foreseeable future. We provide here a summary of those considerations to address comments that our discussion of the M-Opinion in the proposed rule was insufficient and should have been more detailed. We carefully considered both the M-Opinion analysis that we referenced in the proposed rule and the public comments we received on the proposed rule when making the additional revisions to the foreseeable future framework we finalize here. We will continue to consider the following as we determine the extent of the foreseeable future when making classification decisions:

1. Congress intended the Secretary (of the Interior or Commerce) to apply the concept of the foreseeable future based on the facts applicable to the species being considered for listing. Congress purposefully did not set a uniform timeframe for the Secretary's consideration of whether a species was likely to become an endangered species, nor did Congress intend that the Secretary set a uniform timeframe. (*Endangered Species Act of 1973: Hearings on S. 1592 and S. 1983 Before the Senate Subcomm. On the Environment of the Committee on Commerce,* 93d Cong. 51, 58–59, 61, 63, 66 (1973)).

2. In any particular analysis under section 4(a)(1) of the Act, the Secretary has broad discretion with respect to what constitutes the foreseeable future in the context of that analysis, as long as the rationale is articulated.

3. The Secretary's discretion must be exercised consistent with the ordinary meaning of the statutory language and context in which the phrase is used. (*BP Am. Prod. Co.* v. *Burton,* 549 U.S. 84, 91 (2006); *Food & Drug Admin.* v. *Brown & Williams Tobacco Co.,* 529 U.S. 120, 132–33 (2000)).

4. The Secretary's analysis of what constitutes the foreseeable future for a particular listing determination must be rooted in the best available data that allow predictions into the future, and the foreseeable future extends only so far as those predictions are reliable. ''Reliable'' does not mean ''certain''; it means sufficient to provide a reasonable

degree of confidence in the prediction, in light of the conservation purposes of the Act. (*See generally Alaska Oil & Gas Ass'n* v. *Pritzker,* 840 F.3d 671, 681 (9th Cir. 2016)).

5. Because the predictions relate to the status of the species, the data relevant to an analysis of foreseeable future are those that concern the future population trends and threats to the species, and the likely consequences of those threats and trends.

6. Since the foreseeable future is uniquely related to population, status, trends, and threats for each species and since species often face multiple threats, the Secretary is likely to find varying degrees of foreseeability with respect to the various threats. Although the Secretary's conclusion as to the future status of a species may be based on reliable predictions with respect to multiple trends and threats over different periods of time or even threats without specific time periods associated with them, the final conclusion is a synthesis of that information.

7. The Secretary must make the determination of ''threatened status'' based on the best scientific and commercial data available (16 U.S.C. 1533(b)(1)). This may include reliance on the exercise of professional judgment by experts when such judgments are consistent with the concepts laid out in the M-Opinion, including the need to document the basis for the conclusion.

8. The Secretary need not identify the foreseeable future in terms of a specific period of time. Rather, it is important that the information and data used by the Secretary are reliable for the purpose of making predictions with respect to a particular threat. Nevertheless, if the information or data are susceptible to such precision, it may be helpful to identify the time scale being used.

9. With respect to any relevant prediction, when the point is reached that the conclusions concerning the trends or the impacts of a particular threat are based on speculation, rather than reliable prediction, those impacts are not within the foreseeable future. (*E.g., Bennett* v. *Spear,* 520 U.S. 154, 176 (1997); *Bldg. Indus. Ass'n.* v. *Norton,* 247F.3d 1241, 1246–47 (D.C. Cir. 2001)).

10. The administrative record for a decision under section 4(a)(1) of the Act should include more than just a conclusion as to what is foreseeable given the data available; it should also explain how the Secretary reached that conclusion.

Factors Considered in Delisting Species

The June 22, 2023, proposed rule (88 FR 40764) contained a series of revisions to the regulation at 50 CFR 424.11(e), which addresses delisting decisions under the ESA. As we explained in the proposed rule, these changes were intended to clarify multiple aspects of this regulation, which had been revised in 2019. The proposed text for this regulation was as follows:

It is appropriate to delist a species if the Secretary finds, after conducting a status review based on the best scientific and commercial data available, that:

(1) The species is extinct;

(2) The species is recovered or otherwise does not meet the definition of a threatened or endangered species. In making such a determination, the Secretary shall consider the factors and apply the standards set forth in paragraph (c) of this section regarding listing and reclassification; or

(3) The listed entity does not meet the statutory definition of a species.

While many commenters indicated they support the proposed revisions to 50 CFR 424.11(e), many others requested that additional changes be made to further clarify the intent of the proposed revisions and to better indicate or ensure that delisting decisions would be based on sufficient data and a thorough review of the best scientific data available. Following our review and consideration of the public comments, we have modified the text of this regulation to read as follows:

Species will be delisted if the Secretary determines, based on consideration of the factors and standards set forth in paragraph (c) of this section, that the best scientific and commercial data available substantiate that:

(1) The species is extinct;

(2) The species has recovered to the point at which it no longer meets the definition of an endangered species or a threatened species;

(3) New information that has become available since the original listing decision shows the listed entity does not meet the definition of an endangered species or a threatened species; or

(4) New information that has become available since the original listing decision shows the listed entity does not meet the definition of a species.

As indicated in this revised version of 50 CFR 424.11(e), the opening sentence now includes a cross reference to the ''factors and standards'' for making listing determinations, which are set forth in an earlier paragraph (*i.e.,* paragraph (c)) of the implementing regulations. In the proposed rule, this cross reference had appeared only in 50 CFR 424.11(e)(2). This modified opening sentence also includes the more-straightforward wording, ''species will be delisted if,'' in place of the proposed wording, ''it is appropriate to delist a species if''; it also includes slightly different phrasing that indicates the best available data must ''substantiate that'' one of the listed circumstances for delisting has been met. These additional modifications to 50 CFR 424.11 are intended to address various and diverse concerns and comments asserting that the Services could, when making delisting determinations, apply novel factors and standards, base their decision on insufficient scientific evidence, delist species automatically if any of the identified circumstances are met, or purposely delay delisting species even if any of the identified circumstances are met. As revised, the text more clearly indicates that the factors and standards that the Services must consider and apply when listing a species also apply when a species is being evaluated for delisting (*e.g.,* consideration of threats per section 4(a)(1) of the ESA), regardless of the particular circumstances for that species (*e.g.,* extinction, recovery). The revised text also removes potentially confusing language regarding the Services' intentions (*i.e.,* ''it is appropriate to delist'') and better emphasizes that the Services would not promulgate a delisting rule unless the best available data provide sufficient scientific evidence that the species no longer warrants protection under the ESA.

The text in 50 CFR 424.11(e)(2) is also modified from the proposed text to simultaneously address disparate comments and concerns regarding the proposed reinsertion of ''recovery'' into the regulation. Some comments expressed concerns that by reinserting ''recovery'' into the regulation, the Services intend to link delisting to recovery plans or would require recovery plan criteria to be met to delist species. Other comments expressed concerns that by simply inserting a reference to ''recovery'' into an existing provision, the Services are not sufficiently emphasizing recovery of species as a principal goal of the ESA and a principal responsibility of the Services. The modified text for 50 CFR 424.11(e)(2) now sets out recovery as one of the distinct circumstances in which species will be delisted. The modified text also explicitly links ''recovery'' to the definitions of an endangered species and a threatened species to make it clear that the standard for assessing whether a species

is recovered is not exclusively or inextricably linked to any recovery plan criteria; instead, ''recovery'' must be assessed against the definitions of an endangered species and a threatened species in the Act.

We also modified the text to separately list two other potential circumstances for delisting a species, which are now set forth at 50 CFR 424.11(e)(3) and (e)(4). These additional modifications were made in response to comments that the Services were creating vague or novel bases for delisting. We acknowledge that in our effort to simplify and streamline this text in 2019, we removed some of the explanatory context for these circumstances and, as a result, created the false impression that these were novel circumstances for delisting. As this was not our intent, we have modified the text to provide the necessary context for understanding that these other two circumstances for delisting are limited to situations in which new data become available after a species is listed that change the scientific understanding of that species—with respect to either its taxonomy or its status. Scientific understanding of species is often not perfectly or fully resolved at the time of listing; nevertheless, the Services are required to make listing determinations based on the best data available while adhering to statutory time limits. The ESA does not permit the Services to delay or extend these statutory deadlines indefinitely to conduct additional studies or resolve all uncertainties. In cases where we have listed species that are later shown, on the basis of new information, to not be taxonomically valid ''species'' or not be facing risk of extinction, the Services will undertake a rulemaking to propose to delist those species. The revised text at 50 CFR 424.11(e)(3) and (e)(4) is intended to better reflect those circumstances, which both Services have experienced in their years of implementing the ESA (See, *e.g.,* 75 FR 52272, August 25, 2010 (new survey data showed additional populations and greater geographical range of the Utah valvata snail, *Valvata utahensis,* than were known at the time of listing); 86 FR 74378, December 30, 2021 (new genetic and morphological data demonstrated that the listed coral, *Siderastrea glynni,* is synonymous with another coral species)).

In the section below, we provide further discussion and explanations of the changes to 50 CFR 424.11.

Summary of Comments and Responses

Comments on the proposed rule, which published on June 22, 2023 (88 FR 40764), were solicited from all interested parties through August 21, 2023. In addition to requesting comments on the proposed revisions to 50 CFR part 424, we solicited comments on the analyses and conclusions in the Required Determinations section of the proposed rule. We also indicated that we would accept public comments on all aspects of the 2019 rule, including whether any of those provisions should be rescinded in their entirety (restoring the prior regulatory provisions) or revised in a different way.

During the public comment period, we held a series of six informational sessions to provide interested Federal agencies, Tribes, States, nongovernmental organizations, and industry groups an overview of the proposed rule. More than 500 attendees participated in these informational sessions, and we addressed questions from the participants during the sessions. We received and considered several requests for an extension of the 60-day public comment period; however, we decided not to grant these requests because we concluded that 60 days was sufficient to afford the public a meaningful opportunity to comment. The majority of the proposed revisions are to portions of the regulations that were previously revised and thus subjected to public review and comment in 2019, and we had also publicly announced in a press release our intention to revise these regulations in June of 2021.

More than 95,000 comment submissions representing more than 163,000 individual commenters were received by the close of the comment period on August 21, 2023. Comments were received from a range of interested parties, including individual members of the public, States, Tribes, industry organizations, legal foundations and firms, and environmental organizations. The majority of commenters requested that the 2019 rule be rescinded in full. Among the submissions we received were multiple letters from organizations signed by thousands of individuals expressing general opposition to the proposed rule because we had not proposed to rescind or revise some provisions of the 2019 rule. Many of the individual comments we received were non-substantive in nature, expressing either general support for, or opposition to, the proposed rule with no supporting information or analysis, but we also received many detailed substantive comments expressing support for, or opposition to, specific portions of the proposed rule. We reviewed and considered all public comments prior to developing this final rule. Below, we summarize and provide responses to the substantive public comments, and we indicate where we made revisions to the proposed regulations in response to those comments. Similar comments are combined where appropriate. We did not consider, and did not include below, comments that are not relevant to, or that are beyond the scope of, this particular rulemaking or the 2019 rule.

Comments on the Presentation of Economic or Other Impacts

Comment 1: Many commenters expressed support for reinserting ''without reference to possible economic or other impacts'' into the regulatory text, stating that it was most consistent with the plain language of the ESA and would further the science-based conservation purposes of the ESA. Several commenters stated that the 2019 regulations violated congressional intent with respect to the ESA and inappropriately injected economic considerations into listing decisions.

Response: The Services appreciate the support for reinstating ''without reference to possible economic or other impacts'' into the regulatory text related to listing determinations and agree that it is consistent with the Act and congressional intent regarding section 4(b)(1)(A) of the Act. The Act states that determinations under section 4(a)(1) are to be made solely on the basis of the best scientific and commercial data available. Congress added this requirement through amendments to the Act in 1982 (Pub. L. 97–304, October 13, 1982). The legislative history for the 1982 amendments describes the purposes of the amendments using the following language (emphases added): ''to ensure that [listing and delisting] decisions . . . are based *solely* upon biological criteria,'' Conf. Rep. (H.R.) No. 97–835 (1982) (''Conf. Rep.''), at 19; ''to prevent non-biological considerations from affecting [listing and delisting] decisions,'' *id.;* and ''economic considerations *have no relevance to* [listing and delisting] determinations,'' *id.* at 20. See also Rep. 97–657 (H.R. Rep. No. 567, 97th Cong., 2nd Sess. 1982, 1982 United States Code Congressional and Administrative News (U.S.C.C.A.N.). 2807, 2819, 1982 WL 25083, *20).

We find the removal of this language from the regulatory text created the impression, and possibly even expectation, that the Services would compile information regarding the economic impacts of classification

determinations, and it created concerns that the Services would inappropriately consider such information when making classification determinations (*e.g.,* ''Science Loses Ground to Economics with New Endangered Species Act Rules,'' (McGlashen 2019); ''Biodiversity on the Brink: The Consequences of a Weakened Endangered Species Act,'' (Bleau 2020)). For example, during the comment period for the California spotted owl proposed listing rule (88 FR 11600; February 23, 2023), we received a comment (FWS–R8–ES–2022–0166–0052) asking the FWS to ''do their due diligence'' and conduct ''a comprehensive economic analysis that includes evaluation of impacts'' on various stakeholders and activities and stating: ''FWS must refrain from issuing a final decision on whether or not to approve the proposed listing for Spotted Owls until after a comprehensive economic analysis has been completed, and the public has had an opportunity to review said analysis and submit comments on it.'' As it was never our intention to take such information into account when making classification decisions, and doing so would clearly run afoul of the Act, we find that reinstating this regulatory text should help dispel these misperceptions and concerns.

Comment 2: A commenter noted that economic impact analyses are already addressed through other means such as through project planning and National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) compliance for specific projects and should not be included in the listing process.

Response: The Services agree that economic impact analyses for specific projects can be addressed through other means and should not be conducted for listing, delisting, and reclassification decisions, consistent with the clear intent of the Act.

Comment 3: Several commenters stated that the Services are not precluded from compiling data and referring to the economic impact of a listing determination as long as that information is not used in the listing determination. A number of commenters stated that compiling this information and making it available to the public, local and State governments, and stakeholders at the time of listing a species would improve transparency, would allow decision-makers to make better informed choices concerning activities that may affect the species, and may spur voluntary conservation actions. One commenter stated that if the Services restored this language to the regulation, it would prevent them from making decisions that are least cost to small entities.

Response: As we explained in the proposed rule and discuss above in response to *Comment 1,* the removal of this phrase from the regulations in 2019, as well as certain statements made by the Services in the preamble accompanying its proposed removal (see 83 FR 35193 at 35194–95, July 25, 2018), caused confusion regarding the Services' intentions with respect to the collection, presentation, and consideration of economic impact information stemming from the classification of species. In some instances, and as implied by these comments, removal of this language even created the expectation that the Services should consider economic impacts of a listing decision in an effort to minimize the economic impacts of species' listings. However, the Services never intended, as a matter of general or routine practice, to compile, analyze, or present information pertaining to the economic impacts of species classification, and doing so could lead to needless and time-consuming litigation to determine whether any economic impact considerations were improperly taken into account. Restoring the language ''without reference to possible economic or other impacts'' will help eliminate these public expectations and better reflects both the statutory requirements of section 4(b)(1) of the Act and the Services' actual practice.

Comment 4: Some commenters stated that the Services should be compelled to compile data on the economic impact of listing species because all ESA regulatory programs, including listing decisions, must consider economic impacts. One commenter stated the Services should also consider impacts to the human environment in addition to economic impacts. One commenter stated that the Services lack clear authority to omit disclosure of economic impacts from listings.

Response: Congress amended the ESA in 1982 to ensure that listing determinations are based solely on the best scientific and commercial data available. The Act is clear that the Services cannot consider economic impacts when making listing decisions. Likewise, the Act does not permit the Services to consider impacts to the human environment when making listing decisions. The regulation we are finalizing, which is explicitly linked to making listing, reclassification, and delisting determinations under the Act, simply reiterates these existing legal requirements. With respect to the comment that the Services must disclose economic impacts of listing decisions, the Act is clear that listing decisions must be based solely on the best scientific and commercial data available and any impacts that may stem from the classification decision are not to be considered in making the determination. When proposing and finalizing rules to list, reclassify, or delist species, the Services are only required to disclose the data upon which the species classification decision is based (see 16 U.S.C. 1533(b)(8)). The 2019 rule premised the removal of the phrase, in part, on our inherent authority to administer our programs in the interest of public transparency (84 FR 45020 at 45025, August 27, 2019), rather than a specific grant of statutory authority. This goal of transparency was poorly served, however, because we created the problematic impression that the Services would begin to compile information regarding the economic impacts of classification determinations and, further, that the Services might take such information into account directly or indirectly when making classification determinations, which would run afoul of the Act's mandate.

Comment 5: Several commenters suggested the Services could consider economic impacts when making listing determinations. One commenter stated the Services could refrain from listing a species if they determine that because of the economic impact of listing the species, they could leverage more conservation resources from other parties by not listing the species.

Response: The Act requires the Services to make listing determinations solely on the basis of the best scientific and commercial data available. We are not permitted to consider the economic impact of listing a species when making a species classification determination. If, following an assessment of a species' status, a species meets the Act's definition of an endangered species or a threatened species based on the best scientific and commercial data available, the Services are required to list that species regardless of economic impact.

Comment 6: Some commenters stated that the Services had not adequately explained why we reversed our view that the ESA permits us to compile and share economic data about listing decisions. They disagreed that the legislative history cited in our proposed rule supports the Services' rationale. Some commenters stated that we had misinterpreted congressional intent, while others cautioned the Services not to rely too much on legislative history, arguing that if Congress sought to

exclude consideration of economic data or other impacts from listing decisions, it could have done so through statutory language.

Response: When we removed this phrase from the regulations in 2019, we stated that it was not necessary because neither the Act nor the legislative history indicates that Congress intended to completely prohibit the Services from compiling economic information about potential listings, and because there may be circumstances in which referencing economic or other impacts would be informative to the public. We also made clear that we could not consider economic or other impacts in making listing determinations because the Act prohibits it. Based on our subsequent review of the 2019 rule and our experiences implementing it, the language of the Act, and the legislative history, we find that this change created the problematic impression that the Services would begin to compile information regarding the economic impacts of classification determinations and that the Services might take such information into account directly or indirectly when making classification determinations, which would clearly run afoul of the Act's mandate. When evaluating a species' classification status, the Services cannot take into account potential economic impacts that could stem from the classification decision.

As we describe above in response to *Comment 1,* the Act states that determinations under section 4(a)(1) are to be made solely on the basis of the best scientific and commercial data available. Congress added this requirement through amendments to the Act in 1982 (Pub. L. 97–304, October 13, 1982). The legislative history for the 1982 amendments describes the purposes of the amendments using the following language (emphases added): ''to ensure that [listing and delisting] decisions . . . are based *solely* upon biological criteria,'' Conf. Rep., at 19; ''to prevent non-biological considerations from affecting [listing and delisting] decisions,'' *id.;* and ''economic considerations *have no relevance to* [listing and delisting] determinations,'' *id.* at 20. The legislative history for the 1982 amendments is equally clear that use of the term ''commercial data'' was to ''allow the use of trade data'' for purposes of evaluating threats to species and that ''retention of the word 'commercial' is not intended, in any way, to authorize the use of economic considerations in the process of listing a species'' (See H.R. Rep. No. 567 (1982), reprinted in 1982 U.S.C.C.A.N. 2807, 2820, 1982 WL 25083, *20).

As we explained in the June 22, 2023, proposed rule, the removal of this phrase from the regulations, as well as certain statements made by the Services in the preamble accompanying its removal (see 83 FR 35193 at 35194–95, July 25, 2018), caused confusion regarding the Services' intentions with respect to the collection, presentation, and consideration of economic impact information stemming from the classification of species. The Services never intended, as a matter of general or routine practice, to compile, analyze, or present information pertaining to the economic impacts of species classification. However, as a result of removing this phrase, some stakeholders expected us to do just that and provided comments to that end. Restoring this phrase to the regulations addresses this confusion and removes this expectation.

Comment 7: Some commenters stated the proposed regulatory text was contrary to law because ''commercial data'' in the requirement to list species based solely on the best scientific and commercial data available includes economic impacts and the reference to it in the ESA allows flexibility for the Services to account for data that could be considered ''economic'' in nature.

Response: As indicated above, the legislative history of the Act is clear that the phrase ''commercial data'' is ''not intended, in any way, to authorize the use of economic considerations in the process of listing a species'' (H.R. Rep. No. 97–567 (1982), reprinted in 1982 U.S.C.C.A.N. 2807, 2820, 1982 WL 25083, *20. The determination of whether a species should be listed as endangered or threatened must be based on several factors that relate to the species and the threats to its continued existence, but do not include a consideration of the economic effects stemming from the listing, reclassification, or delisting of the species. While the origins of threats to a species may be caused by development or other economic activities, classification determinations are expressly to be made ''solely on the basis of the best scientific and commercial data available'' regarding the threats and the species' response to the threats. The word ''solely'' was added in the 1982 amendments to the Act to clarify that the determination of endangered or threatened status was intended to be made without reference to economic impacts of listing the species. The House committee report (*Id.* at 19–20) elaborated on this point and also stated that ''commercial data'' refers to trade data:

> The principal purpose of the amendments to [s]ection 4 is to ensure that decisions pertaining to the listing and delisting of species are based solely upon biological criteria and to prevent non-biological considerations from affecting such decisions. To accomplish this and other purposes, [s]ection 4(a) is amended in several instances . . . .
>
> Section 4(b) of the Act is amended in several instances by [s]ection 1(a)(2) of H.R. 6133. First, the legislation requires that the Secretary base [her] determinations regarding the listing or delisting of species ''solely'' on the basis of the best scientific and commercial data available to [her]. The addition of the word ''solely'' is intended to remove from the process of the listing or delisting of species any factor not related to the biological status of the species. The Committee strongly believes that economic considerations have no relevance to determinations regarding the status of species . . . .
>
> The Committee did not change this information standard because of its interpretation of the word ''commercial'' to allow the use of trade data. Retention of the word ''commercial'' is not intended, in any way, to authorize the use of economic considerations in the process of listing a species.

The 1982 Conference Report (Conference Report, for Endangered Species Act Amendments of 1982, H.R. No. 97–835, at 19–20 (September 17, 1982)) also underscored the point that the Services must not consider economic information when making classification decisions:

> The principal purpose of these amendments is to ensure that decisions in every phase of the process pertaining to the listing and delisting of species are based solely upon biological criteria and to prevent non-biological considerations from affecting such decisions . . . .
>
> [E]conomic considerations have no relevance to determinations regarding the status of species . . . .

Comment 8: One commenter stated Congress's intent that economic information be compiled at the time of listing is reflected in the ESA's directives that the Services consider ''economic impact[s]'' in establishing critical habitat designations and because the Services are required to designate critical habitat concurrently with listing decisions, we could disclose to the public and potential conservation partners the economic information that is already in the Services' possession or readily available to them.

Response: Section 4(b)(2) of the Act requires that, in the course of designating critical habitat, the Services must consider the economic and other relevant impacts of designating any particular area as critical habitat. Section 4(b)(1) does not permit the Services to consider economic or other

impacts when making a listing determination. The fact that the Services are required to designate critical habitat concurrently with listing a species as endangered or threatened does not mean that Congress intended the Services to compile economic information regarding the impacts of listing a species. In fact, and as discussed above, Congress amended the Act in 1982 to make clear that the Services are to make listing decisions solely on the basis of the best scientific and commercial data available. The Services limit the analysis of the potential economic impact of a critical habitat designation to estimating the economic impacts that could stem from the designation alone, even when the designation is proposed and finalized at the same time as listing. Reinstating the phrase ''without reference to possible economic or other impacts of such determination'' in § 424.11(b) clarifies the Services' longstanding practice and does not preclude the Services from continuing to analyze and present the economic impacts associated with the designation of critical habitat even when the designation is completed concurrently with a species' listing. The reinstated language at § 424.11(b) applies specifically to listing, delisting, and reclassification decisions, as indicated in the regulation, and thus does not prohibit the Services from conducting and presenting economic analyses for other types of rulemakings or actions under the Act, where appropriate.

Comment 9: Several commenters stated that the ESA already prohibits consideration of economic or other impacts when making a listing determination and suggested that adding this language back into the regulations could prevent the disclosure of information needed for the designation of critical habitat.

Response: The Services consider the economic impact of designating an area as critical habitat before an area is designated pursuant to section 4(b)(2) of the Act. The economic impact analysis is made available to the public for review and comment with the proposed rule to designate critical habitat. The reinstatement of the regulatory text preventing the Services from considering economic or other impacts when making listing determinations will have no effect on the compilation or disclosure of information needed for the designation of critical habitat.

Comment 10: One commenter suggested the regulatory text be revised to state: ''The Services are not required to compile economic data, and listing determinations will be made without regard to economic impacts.''

Response: The Services decline to make this suggested change. The Act is clear that the Services are not required to compile economic data when making listing determinations, and the addition of such text is unnecessary. In addition, the suggested text could be potentially confusing to the public because it differs from the text that was in the regulations from 1984 until 2019 and could create the impression that we would compile economic information when making listing determinations.

Comment 11: A commenter suggested the Services should define ''other'' in the proposed regulatory text.

Response: The Services decline to define ''other'' in the phrase ''economic or other impacts.'' ''Other'' in this phrase refers to any impact stemming from the listing determination other than economic impacts. As described in this rulemaking, the Services must make listing, delisting, and reclassification determinations based solely on the best scientific and commercial data available and cannot take into consideration economic or any other impacts stemming from the listing, reclassification, or delisting of a species when making species classification decisions.

Comments on the Foreseeable Future

Comment 12: Commenters expressed general support for the proposed revisions, stating that maintaining a regulatory framework to determine the ''foreseeable future'' is important to ensure consistency and transparency. Additionally, commenters stated that the ''reliable'' standard is appropriate for determining the extent of the foreseeable future, but that more guidance would be needed because the term is subjective and has been applied in different ways since the 2009 M-Opinion was released. Other commenters stated that the Services should rescind the 2019 foreseeable future regulation rather than revise it, and they asserted that the proposed revisions to the regulatory language are confusing and inconsistent with the M-Opinion and the Act.

Response: After review of the foreseeable future regulation and consideration of public comments received, the Services have determined that including it in the regulations is preferred because it codifies some of the key elements of our longstanding interpretation of this term as guided by the M-Opinion and creates binding standards that both Services will apply. The changes we finalize in this rule will help to ensure a consistent interpretation and application of the term ''foreseeable future'' within the context of status reviews and listing decisions. Our use of the phrase in the second sentence, ''make reasonably reliable predictions,'' tracks closely with the text on page 13 of the M-Opinion, which the Services have relied on since 2009. As both the M-Opinion and the foreseeable future regulation indicate, we will describe the foreseeable future on a case-by-case basis. We recognize that there will continue to be some subjectivity assessing what is foreseeable, but each listing determination or rule will have to support that the ''reasonably reliable'' standard has been met. At this time, we do not find that, in addition to the regulation and the M-Opinion, additional guidance on how to interpret the foreseeable future is necessary.

Comment 13: Commenters stated that the Services should ensure that the regulation for determining foreseeable-future timeframes and the subsequent application of that framework are not artificially shortened, particularly when considering listing of long-lived species.

Response: The Services evaluate the extent of the foreseeable future on a case-by-case basis for each species when we assess its classification status and must rely on the best scientific and commercial data available when completing these assessments. As described in the preamble to this final rule, the foreseeable-future timeframe is limited by our ability to make reasonably reliable predictions about threats and the species' responses to the threats. We note that the framework we codify in these regulations reflects and tracks with guidance provided in the M-Opinion. The M-Opinion states that the analysis of what constitutes the foreseeable future for a particular listing determination must be rooted in the best available data that allow predictions into the future, and the foreseeable future extends only so far as those predictions are reliable. For example, to be reliable, predictions and the data on which they rely need not be certain; rather, they must be ''sufficient to provide a reasonable degree of confidence in the prediction'' (M-Opinion, at 13). In addition, as stated in the M-Opinion, ''when the point is reached that the conclusions concerning the trends or the impacts of a particular threat are based on speculation, rather than reliable prediction, those impacts are not within the foreseeable future'' (M-Opinion, at 14). Therefore, just as the Services cannot speculate beyond when we can make reliable predictions, we cannot arbitrarily limit the extent of the foreseeable future. The regulatory framework we finalize today addresses these inherent limitations by reference

to our ability to make reasonably reliable predictions.

Comment 14: Commenters stated that there was not an adequate justification for proposing to revise the foreseeable future framework and noted that the proposed rule did not present examples of confusion or inconsistencies between the M-Opinion and the current regulation.

Response: Our proposed rule provided a clear and sufficient justification for proposing changes to the foreseeable future regulation (88 FR 40764 at 40766–40767, June 22, 2023). As we explained in the proposed rule, the language in the 2019 regulation created confusion regarding the way in which the Services interpret and implement the term ''foreseeable future.'' We discussed how the second sentence in the ''foreseeable future'' paragraph that we had added to the regulations in 2019 (*i.e.,* ''reasonably determine that both the future threats and the species' responses to those threats are likely'') created confusion because it seemed to suggest the Services were adopting a novel requirement to conduct an independent analysis of the status of the species rather than simply articulating how we determine the appropriate timeframe over which to conduct that analysis. The statutory reference to the ''foreseeable future'' sets the time period within which to make the substantive determination about the status of the species (*i.e.,* whether the species is likely to become an endangered species, within the foreseeable future, 16 U.S.C. 1532(20)). The Services must then determine whether a species is ''likely to become an endangered species'' within this timeframe. Confusion with respect to this regulation was evident, as some comments on the 2019 rule expressed concern that the Services would be using a more-stringent standard to determine whether a species was threatened or would be demanding a level of scientific certainty that we had not previously required (see 84 FR 45020 at 45028, August 27, 2019). Other comments on the June 22, 2023, proposed rule stated that we were doing something different from the M-Opinion. We never intended for the regulations to create a different standard from the one explained in the M-Opinion. We reconsidered those points, including our responses to those comments in 2019, in accordance with E.O. 13990. We determined it would be better to eliminate this confusion proactively now and revise the regulatory provision so that it aligns more closely with the M-Opinion rather than taking a ''wait-and-see'' approach to determine whether these identified issues with the 2019 rule would manifest in specific listing determinations.

Comment 15: Commenters that expressed support for a regulation interpreting the ''foreseeable future'' suggested that the Services revise the proposed rule language and offered general concepts and/or specific language. Some commenters stated that the Services should use a specific time period of no longer than 12 to 18 years; others recommended that we use ''commonly accepted timeframes,'' and still others recommended the inclusion of a clear endpoint of the foreseeable future. Some commenters suggested that the Services provide more rigid bounds to the extent of the foreseeable future so that greater consistency could be achieved. Other commenters suggested that we apply timeframes only as far as the five factors in the Act, along with the species' responses to those factors, can be reliably predicted.

Response: As stated above, after reviewing the 2019 regulations setting out the foreseeable future framework and considering the public comments on our proposed revisions to those regulations, we have elected to retain the regulation with the revisions described above. We are declining to use a predetermined number of years or period of time (*e.g.,* seven generations as suggested by a commenter) as a universally applied ''foreseeable future'' for all listings because picking a predetermined number of years would be arbitrary and could preclude the Services from relying on the best scientific and commercial data available. Although some threats might manifest according to certain consistent timeframes, the species' likely responses to those stressors are uniquely related to the particular plant or animal's characteristics, status, trends, habitats, and other operative threats. Furthermore, when multiple threats affect a particular species, these threats may have synergistic effects that are also unique to that particular species. Therefore, we decline to adopt any one particular timeframe to be applied universally to all species in lieu of a regulation that describes how we will identify the foreseeable future timeframe for each species. In addition, consistent implementation of the regulation does not mean that the extent of the foreseeable future will automatically be the same number of years into the future or that it will necessarily be the same for each threat to a particular species. To the extent possible, we will continue to provide information in all listing decisions regarding the particular timeframes used when evaluating threats and a species' risk of extinction in the foreseeable future. Providing such information facilitates the public's ability to evaluate the reasonableness of the Services' listing decisions.

Comment 16: Some commenters recommended rescinding the foreseeable future regulation and using the M-Opinion alone. Those who supported this position stated that the M-Opinion is sufficient for interpreting and applying the foreseeable future. Other commenters disagreed that relying on the M-Opinion alone is sufficient without additional guidance. They further stated that they opposed the use of the M-Opinion alone because it did not go through public notice and comment and as a result it is non-binding.

Response: As stated above, after our review of the 2019 regulations setting out the foreseeable future framework, as well as the public comments on the June 22, 2023, proposed rule, we have elected to retain the ''foreseeable future'' regulation with the further revisions described above. The approach we codify in regulation largely reflects the reasoning in the M-Opinion, which does not have the force of law. Therefore, we conclude that it is preferable to codify language in the regulations that more closely reflects the interpretation of the ESA provided in the M-Opinion, which has guided the Services since 2009. Regulations are also subject to a rigorous review process, and the public provided numerous substantial comments on the proposed revisions that helped to inform our conclusion that retaining a regulation regarding the foreseeable future was ultimately a better solution to our concerns about the existing text than rescission. The M-Opinion will continue to be a helpful resource to both Services' staff and the public and can be read without the risk of conflicting with our regulatory text.

Comment 17: Some commenters were unsupportive of the proposed revision to the second sentence of the foreseeable future regulation; in particular, they disagreed with the phrase in the second sentence (*i.e.,* ''reasonably rely''), stating that the phrase is vague, confusing, and should be revised to be clearer.

Response: As stated above, after our review of the 2019 regulations setting out the foreseeable future framework, as well as the public comments on the June 22, 2023, proposed revisions to those regulations, we have revised the second sentence of the framework to specifically align the text to the M-Opinion as described above. The bulk of the comments received stated that the

M-Opinion was understandable, clear, and conveyed a logical description of the limit of the foreseeable future. The changes we codify track the language in the M-Opinion and will provide a transparent and logical framework that the Services will use when making classification decisions. Responses to additional comments below provide further discussion on this aspect of the revisions to the foreseeable future regulation.

Comment 18: Some commenters favored keeping the current regulatory text for 50 CFR 424.11(d) and specifically stated that they opposed removing the word ''likely'' (in the phrase ''. . . both the future threats and the species' responses to those threats are likely'') because, they asserted, foreseeability is limited to what is likely or must be tied to what is likely. Other commenters supported removal of ''likely'' because it would interfere with the Services' use of the best scientific data available.

Response: As explained in the proposed rule, we found that the use of ''likely'' in the 2019 regulations created confusion and seemed to suggest the Services were adopting a novel requirement to conduct an independent analysis of the status of the species, rather than simply articulating how we determine the appropriate timeframe over which to conduct that analysis. (See also our responses to *Comments 12* and *15*). We agree that, to determine that a species meets the definition of a ''threatened species,'' we must provide a rational explanation of why the particular species is ''*likely* to become an endangered species in the foreseeable future.'' In addition, when determining how far into the future is foreseeable for purposes of determining whether a species is threatened, we are required to rely on the best available scientific information and to provide a rational basis for looking out to that point in the future. The comments on the proposed rule have confirmed the importance of removing the word ''likely'' because commenters clearly inferred that use of that word was intended to create a separate or higher bar for listing decisions. Under the revisions we are now finalizing, the Services will follow longstanding practice and continue to apply the guidance set out in the M-Opinion, and thereby avoid speculation and ensure that the data, information, analysis, and conclusions we rely upon are rationally articulated and fully supported. We find that removing the term ''likely'' revises the regulations in a way that better aligns with the interpretation of the ESA provided in the M-Opinion, continues our longstanding practice, and will result in consistent application of the process we apply to determine what constitutes the foreseeable future. The ultimate conclusion of whether a species meets the Act's definition of a threatened species will still depend on whether it is likely to become an endangered species within that timeframe.

Comment 19: Some commenters expressed concern that the proposed changes would allow the use of inaccurate and biased models and treatment of them as factual and would result in overall inconsistency in determining the foreseeable future. They stated that we should not base decisions on speculation or use computer models based on ''suspicions'' of what the future might look like in hundreds of years, and they further stated that endpoints of models should not define the extent of the foreseeable future.

Response: We agree that we are not permitted to speculate or rely on inaccurate models or limitless timeframes, as suggested by some commenters. Regardless of the regulatory text, the Services are required to base classification decisions solely on the best scientific and commercial data available. Because evaluating a species' status is fact-specific, a case-by-case analysis is required, and we must base our decisions on predictions about the threats and the species' responses to those threats that are reasonable and supported by the best scientific and commercial data available. As described in the M-Opinion, we look not only at the foreseeability of threats, but also at the foreseeability of the impact of the threats on the species. In some cases, foreseeable threats will manifest themselves immediately; in other cases, it may be multiple generations before the manifestation of the threats occurs. In each case, the Secretary must be able to make reasonably reliable predictions about the future. The further into the future that an assessment of threats or species' responses progresses, the greater the burden with respect to explaining how the future remains foreseeable for the period being assessed.

We agree with what the M-Opinion states on this point:

[T]he analysis of what constitutes the foreseeable future for a particular listing determination must be rooted in the best available data that allow predictions into the future, and the foreseeable future extends only so far as those predictions are reliable. ''Reliable'' does not mean ''certain''; it means sufficient to provide a reasonable degree of confidence in the prediction, in light of the conservation purposes of the Act. (M–37021 at 13).

Comment 20: Some commenters opposed removing the phrase ''reasonably determine'' (in the phrase ''The term foreseeable future extends only so far into the future as the Services can reasonably determine that . . .'') because, they argued, the phrase ensures the foreseeable future is not based on vague or speculative information and does not lead to a limitless foreseeable future. Some commenters stated that this proposed revision seems to fully adopt the precautionary principle when deciding to list, which the ESA does not allow.

Response: We have concluded that replacing the proposed phrase ''reasonably rely on information'' with the phrase ''make reasonably reliable predictions'' better aligns the second sentence of the regulation with the language of the statute as explained by the M-Opinion and reflected in the Services' longstanding practice. As explained above and in more detail in the M-Opinion, the statutory language does not permit the Services to base our determinations of the foreseeable future on vague or speculative information and does not lead to a limitless foreseeable future. In implementing this regulation, we will review the degree of certainty and foreseeability concerning each of the threats to the species and the species' responses to those threats. The foreseeable future must be based on the best scientific and commercial data available, and none of the changes finalized here adopt a precautionary approach to listing determinations.

Comment 21: Commenters expressed concern that the proposed regulatory text, if made final, would provide no regulatory certainty, result in limitless foreseeable future timeframes, and lower the ''bar'' on listing species, leading to an increase in species listings.

Response: The Services do not agree that the revised regulatory language will lower the ''bar'' on, or standards for, listing decisions or result in limitless foreseeable futures. As discussed above, the revisions we are finalizing today are consistent with the reasoning in the M-Opinion. Therefore, we are revising the regulation to better align with the interpretation of the statute provided in the M-Opinion that the foreseeable future be based on our ability to make reasonably reliable predictions about the threats and species' responses to those threats.

Comment 22: Commenters questioned the use of the phrase ''reasonably rely'' in the proposed rule language and asked whether the standard for the foreseeable

future should instead be how far into the future the ''best scientific and commercial data available'' goes, based on section 4(b)(1)(A) of the Act.

Response: The commenters are correct that the Services are required to make decisions about species' classification status on the basis of the best scientific and commercial data available. Our implementing regulations at 50 CFR 424.11(c) also restate this requirement and apply it to determinations of the foreseeable future. However, even for analyses or predictions that are based on the best scientific and commercial data, determining the status of any species at some point in the future is inherently challenging because we cannot predict the future with precise certainty. Therefore, we have revised the second sentence of the regulation to include the phrase ''make reasonably reliable predictions'' to indicate how far into the future predictions based on the best scientific and commercial data available can extend. The phrase ''reasonably reliable predictions'' is also consistent with generally applicable administrative law principles that we provide a rational basis for our decision.

Comments on Delisting

Comment 23: Some commenters stated that they support the proposed delisting regulation because it addresses the concern that, under the 2019 regulation, the Services would delist species prematurely. Numerous other commenters, however, requested that we instead rescind the 2019 delisting regulation and reinstate the regulation that had been in place prior to 2019, which the commenters asserted was clearer, better emphasized the goal of recovery, and better ensured a science-based delisting process. Some commenters specifically requested that we provide additional direction for assessing extinction or restore the waiting-period requirement for declaring species extinct, because extinction is not otherwise explained or defined, nor can it be assessed by the Act's section 4(a)(1) factors. Some commenters specifically requested we reinstate the previous regulatory language indicating delisting may be warranted when the original data were in error to ensure such decisions are based on scientific data and not intervening statutory or regulatory changes.

Response: In response to these and other related comments, we have made several changes to the proposed regulation at 50 CFR 424.11(e) to include certain aspects of the regulations that had been in place prior to 2019. For instance, we rephrase two of the listed circumstances to provide more context, which indicate those circumstances are limited to cases in which new data demonstrate the original listing is not accurate. We also rephrase the text to explicitly indicate that delisting is contingent upon whether the best scientific and commercial data substantiate that the species meets one of the identified circumstances. We make these changes because we recognize that in our efforts to simplify and streamline the delisting regulation in 2019, we removed the explanatory context necessary to understand the intent and meaning of specific provisions, and the 2023 proposed rule included too few changes to adequately address that concern and clarify the regulation. We find that this final rule strikes the appropriate balance of being simple and straightforward while also clearly describing the various circumstances for delisting species and more firmly establishing that delisting decisions are science-based decisions.

We do not, however, find it necessary or helpful to include additional regulatory direction or guidance on how to assess extinction. Determinations and assessments to establish whether a species is extinct are inherently fact- and case-specific, and we do not agree that the regulations should establish universally applicable guidance beyond the existing requirement to base our conclusions on the best scientific and commercial data available. We, therefore, find that some of the streamlining of this regulation achieved through the 2019 rule, such as the removal of ambiguous phrasing (*e.g.,* ''a sufficient period of time must be allowed''), is still appropriate. The wording of the regulation finalized in this rule does not undermine the requirement to substantiate the extinction of a species prior to delisting it. Each rulemaking to remove a species from the official Lists must provide the scientific basis for the delisting and must be subject to public review and comment, whether the delisting is due to extinction, recovery, or a change in our understanding of the species due to the availability of new information.

Comment 24: A commenter recommended we delete § 424.11(e) of the regulations because it is unnecessary and the Services should instead rely on section 4(c) of the ESA, which provides the criteria for delisting.

Response: We decline to remove § 424.11(e) of the implementing regulations, because it provides a useful and transparent interpretation of the statutory basis for delisting and identifies the possible circumstances in which a species may be delisted. While section 4(c) of the Act does indicate the basis for review and revision of the Lists of Endangered and Threatened Wildlife and Plants, it does not identify or describe the various circumstances in which delisting may be appropriate. For example, it does not acknowledge extinction as a basis for delisting, nor does it account for the fact that there are instances when new information may become available that alters the original basis for listing, whether it be new information about the species' status or its taxonomy.

Comment 25: Multiple commenters were opposed to the proposed changes to the delisting regulations, and some of these commenters requested that we withdraw the proposed rule. Other commenters noted that if the proposed changes are finalized, the Services should provide a detailed explanation of the factors that will be considered in delisting decisions and include a straightforward process by which recovered species may be expeditiously delisted.

Response: As noted previously and as discussed further in responses to related comments below, we have made several revisions to the proposed delisting regulation. Some of these revisions were made in response to comments stating that aspects of the regulation were confusing, vague, or ambiguous. We find the final delisting regulation is clear with respect to the basis, standards, and circumstances for delisting species. There are no other factors outside of those indicated in this regulation that can or could provide a basis for delisting pursuant to the Act. Straightforward requirements and procedures for proposed and final rules are also already provided at 50 CFR 424.16 and 424.18, and we find no purpose or basis for adding separate or different requirements for delisting rules.

Comment 26: Some commenters asserted that the proposed changes to the delisting regulation were not adequately justified in the proposed rule. The commenters stated that the Services' rationale that these changes are intended as clarifications and to eliminate potential confusion is not credible because the proposed changes are not limited to clarifications, and because the Services did not provide evidence of any confusion stemming from the 2019 rule.

Response: We disagree and find that the proposed rule provided adequate justification for the several changes proposed to the delisting regulations at 50 CFR 424.11(e). For example, in the proposed rule, we stated that some changes were intended to remove the

potential for confusion or concerns that the Services can or will take immediate action to delist a species upon completion of a status review without following notice-and-comment rulemaking procedures or that the outcome of such a rulemaking is predetermined in any way (see 88 FR 40764 at 40767, June 22, 2023). Indications of such confusion and concerns can be found in comments we received and discussed in the 2019 rule (*e.g.,* ''the revised 424.11(e) creates an expedited delisting process,'' 84 FR 45020 at 45038, August 27, 2019), as well as in comments on the recent 2023 proposed rule and discussed herein (see comment summaries below). Thus, there is adequate indication of confusion regarding the text and implications of this regulation, and our decision to finalize additional revisions to this regulation to further reduce or eliminate any confusion with respect to the when and how of delisting actions is well-justified. We determined it would be better to address this confusion proactively and in an effort to be consistent with E.O. 13990's policy of improving protections to the environment rather than taking a ''wait-and-see'' approach to determine whether these identified issues with the 2019 rule would manifest in specific delisting determinations.

In the proposed rule, we also explained that removal of the reference to recovery in the delisting regulations was the focus of many public comments and that commenters expressed concerns that the Services would delist species before they were recovered (see 88 FR 40764 at 40767, June 22, 2023). In the proposed rule, we also indicated that, upon review and reconsideration of the 2019 rule, we now find that it is appropriate and preferable to include ''recovered'' in the delisting regulations as an express, important example of when a species should be delisted. This revision made in this final rule is intended to more clearly indicate that the Services have no intention of delisting species prematurely and that recovering listed species is no less of a priority. As the agencies charged with implementing the Act, we view this change as an important and appropriate clarification to the delisting regulation.

Comment 27: Multiple commenters objected to the proposed removal and replacement of the phrase ''the Secretary shall delist if'' with the phrase ''it is appropriate to delist if'' in the opening sentence of the regulation concerning the delisting process. Many of the commenters opposing this change stated it would remove the directive for the Services to take immediate action to delist species when the specified criteria are met. Some commenters expressed concerns that this proposed rewording would be interpreted as making delisting discretionary or optional, or that it could delay, or allow for purposeful delay of, delisting actions. Commenters stated that delisting is mandatory, because the ESA requires that we delist species when they no longer meet the criteria for listing or when they become extinct; therefore, implying that delisting is discretionary is contrary to the ESA. Other commenters asserted that this change was vague or would create more confusion regarding the process for delisting. Commenters noted that delisting must be treated as a priority and that delisting species in a timely fashion reduces the regulatory burden on the public and helps to better demonstrate the success of the ESA.

Response: As we discussed in the proposed rule, the intention of this particular proposed change was to remove the potential for confusion or concerns that, by inserting the phrase ''the Secretary shall delist if'' into this regulation in 2019, the Services would or could take immediate action to delist a species without following notice-and-comment rulemaking procedures, or that the outcome of such a rulemaking was predetermined. However, based on these and other comments, the text finalized in this rule replaces the phrase ''it is appropriate to delist a species if'' with the more direct phrase, ''species will be delisted if.'' The final text of this regulation better reflects both that the Services have no intention of either purposely delaying delisting actions or circumventing any ESA or Administrative Procedure Act (APA; 5 U.S.C. 551 *et seq.*) requirements. We also note that the Act does not establish strict timelines for removing species from the Lists once a status review is completed. While the Services make every effort to complete delisting rules when supported by the data and evidence, we acknowledge that doing so is contingent upon our available resources. We also note that regardless of how quickly the Services are able to take action to formally remove a species from the list, the Act allows any interested party to petition the Services to do so and thereby compel the Services to take action to consider delisting that species.

Comment 28: Some commenters indicated they oppose removal of the ''shall delist'' phrase from this regulation because it would make the delisting regulation inconsistent with the listing and reclassification regulation at paragraph (c) of § 424.11, which states that ''a species shall be listed or reclassified if . . . .'' Other commenters noted that the ''shall'' phrasing aligns with the language Congress used in section 4 of the ESA. Other commenters supported retaining the ''shall'' clause or other text that would acknowledge the obligation to delist and also recommended additional revisions to indicate that delisting is not automatic and would still involve a rulemaking process. Several commenters recommended regulatory text that would explicitly instruct the Services to initiate the process to delist, and some commenters also suggested that similar language be included in § 424.11(c) with respect to listing and uplisting (*i.e.,* reclassification from a threatened species to an endangered species).

Response: We have considered these comments and the structure of the listing and reclassification regulations at 50 CFR 424.11(c), and we have modified the text of the delisting regulation in this final rule. Specifically, and as already discussed, we have changed the proposed phrasing to instead state that ''species will be delisted if . . . ,'' which matches the structure of the listing and reclassification regulation at 50 CFR 424.11(c). We also note that we have elected to use the verb ''will'' instead of ''shall'' to be consistent with the 2011 Federal Plain Language Guidelines at III.a.1.iv. (available online at *https://www.plainlanguage.gov/media/FederalPLGuidelines.pdf*), which recommend against using ''shall'' due to the term being outdated and imprecise, and the Office of the Federal Register's Principles of Clear Writing (available online at *https://www.archives.gov/federal-register/write/legal-docs/clear-writing.html*), which suggest the use of ''will'' to predict future action. These verbs in no way represent or reflect a difference in terms of the required actions that must be undertaken by the Services when listing, reclassifying, or delisting species.

We do not find it necessary or consistent with the Act or 50 CFR 424.11(c) to include additional text to indicate any specific requirements for initiating rulemaking. Those requirements are already provided in section 4 of the ESA, the APA, and 50 CFR 424.16 and 424.18. For these same reasons, we also decline to revise the implementing regulation at 50 CFR 424.11(c) to include instructions for initiating rulemakings to list and reclassify species.

Comment 29: Multiple commenters expressed support for removing the phrase stating the ''Secretary shall delist if'' and replacing it with the phrase ''it

is appropriate to delist if'' to avoid implying that delisting is a foregone conclusion without agency discretion or public comment. Some commenters stated that this proposed change appropriately reflects that the delisting process must be based not only on a status review using the best scientific and commercial data available but also on a subsequent notice-and-comment rulemaking, rather than imposing or implying a requirement to delist a species immediately following a status review. Some commenters, however, stated this proposed change did not go far enough and that the regulations should also state that species can only be delisted through the process indicated at 50 CFR 424.16(c). Another commenter requested we rephrase the proposed regulation to state ''it is appropriate to consider delisting a species if'' to further alleviate concerns that the Services would take immediate action to delist species when one of the listed circumstances is met.

Response: We appreciate the comments in support of the proposed regulation. However, as noted above and in response to other comments we received, we have made several modifications to the regulatory text to more closely align this section of the regulations with the listing and reclassification regulation at 50 CFR 424.11(c), and to more clearly indicate that we will delist species when the best available data substantiate that decision. We find that the wording of the final regulation best reflects the Services' intention that delistings be neither premature nor purposely delayed. As finalized in this rule, the regulations are clear that removal of a species from the Lists requires a status review, consideration of the factors listed in section 4(a)(1) of the Act, application of the best available data, and notice-and-comment rulemaking.

Comment 30: Multiple commenters indicated they support the proposed reference to recovery in the delisting regulation because it acknowledges that recovery is a fundamental objective of the ESA and represents an important pathway to delisting. Some commenters indicated they support this proposed change because it encourages the Services to delist species when they have recovered. Some commenters stated that removal of this term from the regulation in 2019 had appeared to circumvent recovery plans or make section 4(f) of the ESA meaningless.

Response: We appreciate these comments in support of inclusion of recovery as a circumstance in which a species should be delisted. We also reiterate that although the delisting regulation does not specifically refer to section 4(f) of Act, the statutory requirement to develop recovery plans pursuant to section 4(f) of the Act remains a priority for the Services; recovery plans will continue to be an important tool for guiding, tracking, and implementing conservation actions. This final regulation explicitly refers to recovery but also makes it clear that the delisting of a species requires a status review of that species, consideration of threats as outlined in section 4(a)(1) of the Act, and scientific and commercial data that substantiate that the species is no longer endangered or threatened.

Comment 31: Some commenters noted they support acknowledging recovery in the delisting regulation but stated the proposed regulation does not sufficiently emphasize recovery as the ultimate goal of the ESA. Some commenters requested that the regulation specifically state that recovery is a primary reason for delisting. Several commenters asserted the Services' goal of acknowledging the importance of recovery is undermined or diminished by the proposed insertion of the term ''recovered'' into the phrase ''or otherwise does not meet the definition of a threatened or endangered species.''

Response: We have addressed some of these comments in the final delisting regulation, which includes the modified phrase, ''The species has recovered to the point at which it no longer meets the definition of an endangered species or a threatened species.'' In contrast to the phrasing in the proposed rule (*i.e.,* ''The species is recovered or otherwise does not meet the definition of a threatened or endangered species''), the phrasing of the final regulation appropriately identifies species' recovery as one of the separate, distinct circumstances in which species should be delisted. We decline to make other revisions requested by these commenters, however, because we do not agree that the implementing regulations are the appropriate place to provide a discussion or characterizations of the goals or purposes of the Act, nor do we find it necessary to do so.

Comment 32: Several commenters described the proposed insertion of ''is recovered'' in this regulation as vague, ambiguous, or confusing. Commenters requested that we reword the text to be clearer, include a definition of ''recovered,'' or adopt more-specific regulatory text indicating delisting is warranted after a species has recovered or has met recovery plan objectives. Some commenters stated that linking the regulation to recovery plan criteria would also trigger a delisting action when a recovery plan's objectives are met and would, therefore, likely lead to significantly more buy-in for advancing recovery plan goals. In contrast, other commenters stated that, although they support acknowledging recovery as a basis for delisting, the Services should add language to explicitly indicate that species do not have to meet the specific criteria set forth in a recovery plan in order to be delisted, as such a requirement is not supported by the ESA, the implementing regulations, or existing case law.

Response: In response to the comments describing the proposed revision as confusing and vague, as well as other comments received on the proposed text, we have modified the text in the final regulation. Specifically, we have rephrased the text to read: ''The species has recovered to the point at which it no longer meets the definition of an endangered species or a threatened species.'' We find this statement is clear on its face and further instruction or guidance is not necessary: the terms ''endangered species'' and ''threatened species'' are defined in section 3 of the Act, and the standards and requirements the Services must apply when making listing, reclassification, and delisting decisions are set forth in section 4(a) and (b) of the Act.

As we have acknowledged previously and as supported by existing case law, recovery plan criteria are not binding and cannot in all cases serve as a measure by which the Services can judge the status of a listed species (See *Ctr. for Biological Diversity* v. *Haaland,* 58 F.4th 412, 418 (9th Cir. 2023); *Friends of the Blackwater* v. *Salazar,* 691 F.3d 428, 432–34 (D.C. Cir. 2012); see also *Ctr. for Biological Diversity* v. *Bernhardt,* 509 F. Supp. 3d 1256, 1267 (D. Mont. 2020); *Fund for Animals, Inc.* v. *Rice,* 85 F.3d 535, 547 (11th Cir. 1996) (''Section 1533(f) makes it plain that recovery plans are for guidance purposes only.'')). Thus, we do not find it necessary to make any of the other requested changes to indicate that recovery plan criteria must be met, or do not have to be met, to delist a species as a result of its recovery. We also do not find it necessary to insert a definition of ''recovered'' into this section of the regulations because the term ''recovery'' is already defined in our joint implementing regulations in 50 CFR 402.02 as ''improvement in the status of listed species to the point at which listing is no longer appropriate under the criteria set out in section 4(a)(1) of the Act.'').

Comment 33: Some commenters indicated their support for the proposed reference to ''recovery'' but asserted that

the Services are missing the opportunity to provide additional requirements that recovery goals be clear, consistent, measurable, and based on the best available science, to ensure that the long-term health and viability of recovered species will be maintained after they are returned to State management. Another commenter stated that recovery plans should be updated periodically to address current conditions and new threats.

Response: We appreciate the commenters' feedback on recovery plans; however, regulatory requirements for recovery plans are outside the scope of this current rulemaking. Therefore, we have not added additional text to this final rule to address the content of recovery plans or the process or frequency with which the Services will update recovery plans. The Services do not have joint implementing regulations addressing section 4(f) of the Act; however, both agencies have developed detailed guidance on recovery planning and implementation. Those documents are available online (see *https://www.fisheries.noaa.gov/resource/document/nmfs-recovery-planning-handbook-version-10;* and *https://www.fws.gov/media/interim-endangered-and-threatened-species-recovery-planning-guidance*). We also note that both Services release draft recovery plans for public review and comment prior to issuing final plans; this provides the public with the opportunity to provide specific input to help ensure plans contain clear, measurable, scientifically sound management actions and criteria.

Comment 34: Multiple commenters stated they opposed the proposed reference to recovery in the delisting regulations. Some of these commenters stated this change was unnecessary because the regulations already sufficiently cover the circumstance of species recovery. A commenter asserted this proposed change is confusing because a species may no longer meet the definition of an endangered or a threatened species yet not be fully recovered, *i.e.,* the species may still require conservation actions to be self-sustaining.

Response: We agree that the delisting regulation, as finalized in 2019, did inherently cover the circumstance of recovery as a basis for delisting; however, and as explained in the proposed rule, removal of the reference to recovery from this regulation in 2019 created concerns that the Services would delist species before they were truly recovered or would no longer prioritize recovery planning or recovery efforts in general. We have no intention to diminish or undermine the critical role that recovery plans play in guiding, tracking, and facilitating conservation actions. Because recovery (*i.e.,* conservation) of listed species is a principal goal of the Act and a clearly legitimate basis for delisting species, we conclude it is better and clearer to explicitly refer to recovery in our delisting regulation (see also response to *Comment 36,* below).

The Services have defined ''recovery'' to mean ''improvement in the status of listed species to the point at which listing is no longer appropriate under the criteria set out in section 4(a)(1) of the Act'' (50 CFR 402.02). Under this regulatory definition, which informs how we construe this term under the section 424 regulations, for a species to be considered recovered, it must no longer be an endangered or a threatened species. Thus, we disagree with the comment that the text of the regulation is confusing.

Comment 35: Multiple commenters objected to reinserting ''recovery'' into the delisting regulations and stated that it adds a factor that is not indicated in section 4(a)(1) of the ESA and adds a new or heightened standard that is inconsistent with the ESA. The commenters noted that the existing regulation is clear and that adding the term ''recovery'' to the regulations would create confusion regarding the delisting process, which can only be based on the factors and standards outlined in section 4 of the ESA and is not contingent on meeting a separate recovery standard. Commenters stated that because recovery is not a statutorily permissible basis for delisting, ''recovery'' has no independent meaning in the regulation and is thus purposeless. Some commenters expressed the concern that insertion of this term would result in making recovery plans a requirement for delisting or would lead to the need for the Services to demonstrate that a recovery plan's criteria have been met to delist a species.

Response: We agree with the commenters that the criteria set forth in a recovery plan do not establish the standards for delisting species; those standards are instead set forth in section 4(a) and (b) of the Act. However, recovering endangered and threatened species is one of the primary goals of the ESA, and a recovered status (*i.e.,* when a species no longer meets the definition of an endangered or a threatened species) is a valid circumstance in which a species should be delisted. (See H.R. Rep. No. 95–1625, at 5 (1978) (''The primary purpose of the Endangered Species Act of 1973 is to prevent animal and plant species endangerment and extinction caused by man's influence on ecosystems, and to return the species to the point where they are viable components of their ecosystems.''); *Alaska* v. *Lubchenco,* 723 F.3d 1043, 1054 (9th Cir. 2013) (''The goal of the ESA is not just to ensure survival, but to ensure that the species recovers to the point it can be delisted.'' (citations omitted))). Thus, we find that including recovery as an express example of when delisting is warranted is not only appropriate but entirely consistent with the Act. We, therefore, also find that including the reference to recovery has both purpose and meaning.

This final rule, which has been modified from the proposed rule, is consistent with the Act and existing case law, and in no way requires that recovery plan criteria are satisfied before the species may be delisted (see generally *Friends of the Blackwater* v. *Salazar,* 691 F.3d 428 (D.C. Cir. 2012); *Ctr. for Biological Diversity* v. *Bernhardt,* 509 F. Supp. 3d 1256, 1267 (D. Mont. 2020) (''. . . recovery plans do not bind an agency into any single course of action''); *Fund for Animals, Inc.* v. *Rice,* 85 F.3d 535, 547 (11th Cir. 1996) (''Section 1533(f) makes it plain that recovery plans are for guidance purposes only.'')). The final delisting regulation also very clearly links the concept of recovery to the Act's definitions of endangered species and threatened species, the section 4(a)(1) factors in the Act, and the requirement to base the status review on the best scientific and commercial data. Thus, this regulation does not create the need for the Services to demonstrate that a recovery plan's criteria have been met to delist a species.

Comment 36: Some commenters stated that the justification for inserting the term ''recovery''—to acknowledge one of the principal goals of the ESA—was erroneous, because Congress did not use the term ''recovery'' when outlining the purposes of the Act in section 2 or when defining the terms ''conserve, conserving, and conservation'' in section 3. Some commenters asserted that the Services were overstating the role of recovery plans in decisions regarding downlisting and delisting and stated they are guidance documents only.

Response: We acknowledge that Congress did not use the term ''recovery'' in section 2 of the Act when it outlined the goals of this Act, or in section 3 of the Act, where it defined the terms ''conserve, conserving, and conservation.'' For nearly 40 years, the Services have, however, used a regulatory definition of ''recovery'' that

clearly establishes that this term refers to a condition in which a species has improved, or has been conserved, such that it no longer warrants protection under the Act (see 50 CFR 402.02; 51 FR 19926 at 19958, June 3, 1986). Therefore, we do not find it erroneous to use this term in a manner consistent with its regulatory definition in 50 CFR 402.02 of our joint implementing regulations.

As the delisting regulation in 50 CFR 424.11(e) makes no reference to recovery plans or section 4(f) of the Act, we do not agree that the regulation overstates the role of recovery plans; rather it makes no statement about them at all.

Comment 37: Some commenters requested additional revisions to the regulation to ensure the Services can apply a precautionary approach when making delisting decisions. These commenters asserted that it should be easier to list species than to delist them and that additional changes to the regulations should be made to correct the false equivalency between listing and delisting. Some commenters requested that the regulations include a statement that, when there is reasonable uncertainty, the Services should err against delisting. Commenters also requested that the regulations be modified to indicate that a higher level of certainty and standards is required for delisting compared to those specified in 50 CFR 424.11(c) for listing and reclassifying species.

Response: We decline to make the additional requested revisions, because such revisions would not, in our view, be consistent with the Act and existing case law. As we have stated previously in response to similar comments in 2019 (84 FR 45020 at 45035, August 27, 2019), the Act directs the Services to make determinations regarding whether a species is endangered or threatened based on the best scientific and commercial data available and by applying the factors and standards in section 4(a) and (b) of the Act. The same set of standards applies and the same level of certainty is required regardless of whether we are making a listing determination or delisting determination. In either a listing or delisting context, the Services must substantiate their determination based solely on the best available data. Similarly, if there is sufficient uncertainty regarding the status of a species, the Services could not support a listing determination, nor a delisting determination (*Humane Soc'y of the U.S.* v. *Zinke,* 865 F.3d 585, 597 (D.C. Cir. 2017) (''In addition, the statute requires the Service to attend to both parts of the listing process—the initial listing, and the revision or delisting—with equal care. . . . Nothing in the statutory text compels the Service to put a thumb on the scale in favor of listing, nor does the text require the Service to temporize when the best evidence indicates that a revision is warranted.'')).

As with listing determinations, when considering whether to delist a species, the Services are required to take into account the best available data and information relevant to assessing the species' status and risk of extinction, including prior findings and the discussion of facts supporting those findings, and discuss how the available information supports the conclusions in a well-reasoned, transparent manner. We acknowledge that the factual analyses in the two contexts may differ: in determining whether to list a species, we can generally rely on past and current data and trends regarding the species and the threats to the species to determine whether the species meets the definition of an endangered or a threatened species; but, in cases where a species may have recovered, determining whether to delist a species also requires that we assess the status of the species in the hypothetical absence of protections it currently receives under the Act. Nevertheless, the underlying standards and obligation of the Services to articulate a rational connection between their conclusions and facts in the record are still the same regardless of the context of the determination being made (listing or delisting).

Comment 38: Some commenters stated that the proposed removal of the word ''same'' from the phrase ''the Secretary shall consider the same factors and apply the same standards'' was not substantiated and is unnecessary. The commenters stated there is no evidence that this regulation has caused the ''possible'' confusion discussed in the proposed rule. The commenters stated that rather than eliminate possible confusion, this proposed change would create new confusion about whether the Services intend to consider different factors and apply different standards depending on whether we are considering a species' listing, delisting, or reclassification. Commenters stated that it is important that the Services remain clear that the five factors in section 4(a)(1) of the Act are the same when listing a species and when delisting a species, and that this proposed change would not expand or otherwise revise the criteria that may be considered when determining whether to delist a species.

Response: As we outlined in the proposed rule, this revision eliminates the possible, though unintended, confusion that the delisting analysis is limited to those same, specific factors or threats that initially led us to list that particular species. We find that elimination of possible misinterpretation of our regulations is an appropriate and adequate justification for making this minor wording change. As we have stated in response to other comments, we are not obligated to wait to take action to address confusion until it manifests itself in specific circumstances. The possible confusion here could present a serious issue, as an overly literal reading of the 2019 rule could lead to a premature delisting of a species for whom protections under the Act are still warranted. Resolving this issue now, with a simple word change, is appropriate and consistent with E.O. 13990. The regulation also clearly and plainly states that delisting decisions will be based on consideration of the factors and standards set forth in paragraph (c) of § 424.11. The cross-referenced paragraph (c) identifies the factors and standards that must be applied when listing and reclassifying species, which correspond to the factors and standards set forth in section 4 of the Act. Therefore, removal of the word ''same'' does not allow the Services to apply different requirements, standards, or factors depending on whether we are making listing, reclassification, or delisting decisions.

Comment 39: Multiple commenters agreed with the proposed removal of the word ''same'' from the delisting regulation because it would help eliminate any possible confusion that the delisting analysis is limited to the specific factors or threats that led to the need to list the species. Commenters stated this change makes it clear that the analysis must be conducted on all the threats facing the species at the time of the analysis, not only on the threats that were present at the time of listing. One commenter pointed to specific examples of listed species for which the types of threats affecting the species has changed or increased since the time of their listing. A commenter noted that this proposed change is consistent with the best available science standard and appropriately allows the Services to consider additional information that may arise after a Services' listing determination that supports their decision—whether that be keeping the species on the Lists or delisting it.

Response: We appreciate and agree with these comments.

Comment 40: Some commenters stated that the circumstances for delisting identified in the regulation should be limited to extinction and recovery, and that the other vague factors should not be considered. Some commenters disagreed with including the species ''does not meet the statutory definition of a species'' as a circumstance in which the Services may delist a species, because such inquiries are no longer limited to the data that were available to the Services at the time of listing. Instead, the commenters asserted, this provision would allow for delisting based on other considerations, such as changes in policies or regulations governing the ESA.

Response: In response to these comments, we have modified the text of the regulation to clarify that the particular circumstance referenced by the commenters is limited to instances in which new data indicate the original listing can no longer be considered accurate or valid. Specifically, the regulation now states: ''New information that has become available since the original listing decision shows the listed entity does not meet the definition of a species.'' Under the Act, the Services can only list ''species,'' a term which is defined in the Act to include subspecies of fish, wildlife, and plants, and distinct population segments of vertebrates (16 U.S.C. 1532(16)). Although infrequent, there have been instances in which the Services have removed ''species'' from the Lists because scientific information that subsequently became available showed that the listed entity had been misclassified or incorrectly identified as a unique species. For instance, after the foreign coral, *Siderastrea glynni,* was listed as an endangered species in 2015, new genetic and morphological information became available that demonstrated that *S. glynni* was not a unique species or subspecies and was instead synonymous with another coral species. Based on this information, *S. glynni* did not meet the statutory definition of a species, and it was on this basis that NMFS delisted it in 2021 (see 86 FR 74378, December 30, 2021).

Comment 41: Some commenters noted that the factors listed in section 4(a)(1) of the ESA address threats only, and that although threats must be addressed before a species is delisted, the section 4(a)(1) factors do not provide science-based factors for delisting. Other commenters stated that a review of the listing factors alone could fail to adequately consider a population's long-term stability and thus potentially result in premature delisting.

Response: We agree that the section 4(a)(1) factors address threats only; however, in addition to considering the threats listed in section 4(a)(1) of the Act, delisting determinations must also be made in accordance with section 4(b) of the Act, which requires a review of the species' status based on the best scientific and commercial data available (16 U.S.C. 1533(b)(1)(A)). We also note that under factor (E) of section 4(a)(1) of the Act, which includes ''other natural or manmade factors,'' the Services routinely consider potential demographic threats (*e.g.,* low abundance, declining population trends, limited genetic diversity, limited or disconnected distribution) and factor those types of threats into their assessment of the species' risk of extinction.

Comments on Not-Prudent Determinations

Comment 42: Multiple commenters supported our proposed removal of the second part of § 424.12(a)(1)(ii), which established in 2019 the circumstance that a designation of critical habitat may be not prudent when the threats to the species' habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act. Commenters supported removal of this provision because they felt it would increase the protections provided to species through designation of critical habitat and allow for the full benefit of critical habitat designations to be realized. Commenters supported our proposal because of their concern that this provision allowed the Services to decline to designate critical habitat for species when climate change is a primary threat. They also stated that declining to designate critical habitat when climate change is a primary threat could thwart the conservation purposes of the Act and undermine the efficacy of critical habitat designations. Commenters also expressed the opinion that allowing the Services not to designate critical habitat when climate change is a primary threat was not supported by court decisions.

Response: We appreciate the support of these commenters. They raised many of the same concerns that we detailed in our proposed rule, and we agree that removing this provision is a better way to advance the conservation of endangered species and threatened species, particularly in the face of the ongoing climate crisis.

In our 2019 rule, we stated that we did not intend for the revisions either to suggest that as a standard practice we would find that designating critical habitat is not prudent for species that are primarily threatened by impacts related to climate change, or to preclude us from designating critical habitat whenever the effects from climate change are a primary threat to the species (84 FR 45020 at 45042, August 27, 2019). Further, we explained that we will not prejudge outcomes associated with future potential section 7 consultations because the analysis will be based on whether the threats *can be*—not whether they *will be*—addressed by management actions resulting from consultation (*e.g.,* id. at 45043). However, upon further review and as discussed in the 2023 proposed rule (88 FR 40764, June 22, 2023), we find that this clause did, in fact, require that the Services presuppose the scope and outcomes of future section 7 consultations under the Act, and did suggest that the only conservation benefits of a critical habitat designation are through the section 7 process, a presumption not supported by the language of the Act or court decisions. The public has also interpreted this language as allowing the Services to regularly decline to designate critical habitat for species threatened by climate change, which was not our intent (*e.g.,* see Delach 2019, *https://www.realclearpolitics.com/articles/2019/08/28/new_trump_rules_will_abet_loss_of_climate-threatened_species_141107.html*). Therefore, we conclude that removing this provision is appropriate. As we stated in the preambles to our 2019 rule and 2023 proposed rule, we anticipate not-prudent determinations will continue to be rare, consistent with congressional intent (*e.g.,* S. Rep. 106–126, at 4 (1999), 1999 WL 33592886).

Comment 43: Multiple commenters expressed opposition to our proposed removal of the second part of § 424.12(a)(1)(ii), which established in 2019 the circumstance that a designation of critical habitat may be not prudent when the threats to the species' habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act. Some commenters suggested the removal of the provision will result in changes to how we designate critical habitat. For example, commenters stated the Services will consider effects of climate change even when the true effects are unknown. Other commenters suggested the removal would create a potential for the Services to designate vast areas, undermining the effectiveness of critical habitat by making it less likely that a section 7

consultation on any particular project would result in a determination of destruction or adverse modification.

Other commenters opposed the proposed removal of the provision based on concerns about increased regulatory burden. They stated that considering effects of climate change or other, non-anthropogenic, threats when designating critical habitat may result in unnecessary impacts to regulated entities without any benefits to species. Other commenters stated that removing the provision could create an unintended regulatory burden for project proponents during section 7 consultation because the proponents could be held responsible to address impacts, like those stemming solely from climate change, that are entirely outside of their control.

Response: As discussed in our previous response, both the Act and case law indicate that ''not prudent'' determinations are rare outcomes; the Act requires that the Services designate critical habitat to the maximum extent prudent and determinable when we list species and that we base critical habitat determinations on the best scientific data available. In most instances, the Services have designated critical habitat for listed species that occur within U.S. jurisdiction. The removal of this provision affects whether there is a designation of critical habitat; it does not affect how critical habitat could or would be designated. Therefore, we do not agree that removal of this particular provision in 50 CFR 424.12(a)(1)(ii) will change the size or scope of critical habitat designations.

Climate change affects different species in different ways, and in some cases we may have clear evidence that climate change has altered habitats within the species' occupied range and is causing extirpations and range shifts (*e.g.,* Quino checkerspot butterfly; 74 FR 28776, June 17, 2009). Where the scientific data available support that areas contain essential features (*i.e.,* the ''physical or biological features essential to the conservation of the species'') or that the areas themselves are essential for the conservation of the species, it is important and appropriate that the Services be able to designate those areas. To ignore the impacts from climate change or to establish a general principle of not designating critical habitat if we cannot address habitat-related threats to the species through section 7 of the Act (*e.g.,* climate change) would undermine the conservation purposes of the Act and would not have a rational basis.

Section 7(a)(2) requires that Federal agencies ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of their critical habitat. Specific provisions in the section 7 implementing regulations (*e.g.,* 50 CFR 402.14(i)(2)) safeguard against scenarios where a project proponent would be held responsible for finding a solution to an issue like climate change, which operates on a global scale and is caused by many contributing factors. However, reasonably foreseeable climate-change effects themselves may well be relevant to analyzing effects of an action on listed species and critical habitat and could potentially necessitate changes in project design and operation. Nothing in the implementing regulations for section 4 of the ESA changes the operation of the section 7 consultation process.

Comment 44: Commenters stated that the current not-prudent circumstance at § 424.12(a)(1)(ii) (the present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species) confuses the threats to the species—which form the basis for listing the species—with the protections that are needed to conserve the species—which form the basis for designating the species' critical habitat. Some of these commenters recommended that we remove § 424.12(a)(1)(ii) entirely, while others suggested that we modify this provision to include that designation of critical habitat would not be prudent if habitat loss or impacts are not a ''significant'' or ''primary'' threat. Still other commenters stated the current § 424.12(a)(1)(ii) should be modified to address the court's decision invalidating the FWS's not-prudent determination for the rusty patched bumble bee (*Natural Res. Def. Council* v. *U.S. FWS,* No. 21–0770(ABJ), 2023 WL 5174337 (D.D.C. August 11, 2023)). Commenters also pointed out that in the absence of habitat-based threats, critical habitat can still be an important tool to help a species overcome non-habitat-based threats.

Response: We are finalizing § 424.12(a)(1)(ii) as proposed, which will continue to provide that the Services may find it is not prudent to designate critical habitat in situations when the present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species. While the provision in § 424.12(a)(1)(ii), which has been in the regulations since 2016 (81 FR 7414, February 11, 2016), is intended to reduce the burden of regulation in rare circumstances in which designating critical habitat does not contribute to conserving the species, the Services recognize the value of critical habitat as a conservation tool and expect to designate it in most cases. In addition, as the introductory text of this section of the regulations indicates, the Services are not required to make a not-prudent determination merely because one of the listed circumstances occurs; all of the enumerated not-prudent circumstances are discretionary, and the Services would have to articulate a well-reasoned explanation for exercising that discretion to determine that a specific designation is not prudent.

The court's decision in the rusty patched bumble bee case does not preclude the Services from retaining § 424.12(a)(1)(ii)—the not-prudent circumstance for when the present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species. In vacating and remanding the not-prudent determination in that case, the court did not invalidate the regulatory not-prudent circumstance that FWS had applied, but rather concluded that the record had failed to set forth a reasoned basis for the determination (2023 WL 5174337, at 14).

Comment 45: Commenters stated that critical habitat is an important component of recovery planning and implementation success, and that the only circumstance in which critical habitat should not be designated is when a critical habitat designation would increase the risk of take or otherwise harm a species because of the designation.

Response: The Services agree that critical habitat is an important regulatory tool that contributes to the conservation and recovery of species, and that instances when designating critical habitat is not prudent should be, and are, rare (H.R. Rep. No. 97–1625, at 16–18 (1978); *Natural Res. Def. Council* v. *U.S. Dep't of the Interior,* 113 F.3d 1121, 1126 (9th Cir. 1997); *N. Spotted Owl* v. *Lujan,* 758 F. Supp. 621, 625–26 (W.D. Wash. 1991)).

Most not-prudent determinations have resulted from the Services finding that there would be increased harm or threats to a species as a consequence of identifying where the species occurs or identifying areas that are essential to the species. For example, when a species is highly prized for collection or trade, then identifying specific localities where the species occurs could render it more vulnerable to collection and, therefore, further increase threats to it. Nonetheless, Congress did not limit ''not prudent'' findings to those situations, and other circumstances may arise where a designation is not prudent

for the particular listed species. However, and as the Services' record indicates, in most cases we will find that a designation of critical habitat will further the conservation of the species and will be designated.

Comment 46: Commenters expressed concern that the Services intend to designate critical habitat in situations where there would be no conservation benefit to the species.

Response: The Services disagree that we would designate critical habitat when there would be no conservation benefit to the species. Critical habitat is an important tool that we use to conserve endangered species and threatened species. The Act establishes a requirement for us to designate critical habitat to the maximum extent prudent and determinable at the time a species is listed or finalize a designation of critical habitat within 1 year of the final listing rule. This statutory requirement is not limited to situations when there is a specific conservation benefit from designating critical habitat. Moreover, in most cases, and aside from protections afforded under section 7 of the Act, designation of critical habitat does provide other conservation benefits, for instance through informing management partners of important habitats, stimulating scientific surveys or research, promoting voluntary conservation actions, and raising public awareness of habitats that are essential for the conservation of a species.

Comment 47: Some commenters indicated they support the removal of § 424.12(a)(1)(v), which allowed for not-prudent determinations when the Secretary ''otherwise determines that designation of critical habitat would not be prudent based on the best scientific data available,'' but oppose the proposed change at § 424.12(a)(1) to make the list of not-prudent circumstances not exhaustive. Specifically, commenters stated that making the list of circumstances non-exhaustive is no change from the current regulations and allows the Secretary unlimited discretion to determine critical habitat is not prudent. Commenters stated that the non-exhaustive nature of the list of circumstances would not provide clarity or certainty to the public and that it would be contrary to the legislative history that makes clear Congress intended for not-prudent determinations to be rare and used only for circumstances when designation would harm a listed species. Other commenters stated they support the catch-all nature of the proposed rule text, stating that the Act provides flexibility to the Services to make not-prudent determinations.

Response: As discussed in the 2023 proposed rule, setting this text out separately within the list of circumstances in which the Secretary could potentially make a not-prudent determination inadvertently gave the appearance that the Services might overstep their authority under the Act by issuing ''not prudent'' determinations for any number of unspecified reasons that may be inconsistent with the purposes of the Act. As this was not our intention, we are removing the circumstance set out in § 424.12(a)(1)(v). However, we cannot foresee all possible circumstances in which critical habitat may not be prudent, and making the list of circumstances non-exhaustive provides for the ability to address those circumstances should they arise.

The question regarding whether designating critical habitat is not prudent must be addressed on a case-by-case basis. Any future proposed rule that includes a not-prudent determination will clearly lay out the Services' rationale as to why a not-prudent determination is appropriate in that particular circumstance. In some situations, the Services may conclude, after a review of the best available scientific data, that a designation would nevertheless be prudent even in the enumerated circumstances. Congress recognized that for some species it may not be prudent to designate critical habitat, but the Act does not define or provide specificity with respect to when designation of critical habitat might not be prudent. Section 424.12(a)(1)(i), (ii), (iii), and (iv) partially fill in that gap by identifying general circumstances for when designation of critical habitat may not be prudent. Making the list of circumstances non-exhaustive does not allow the Services to circumvent the clear direction of the Act (*i.e.,* to designate critical habitat) without adequate and rational justification. Any determination that critical habitat is not prudent must be based on the best scientific data available and an evaluation of the fact-specific information for the individual species. As stated elsewhere, we expect it to continue to be rare that we would find a designation of critical habitat to be not prudent.

Comment 48: Commenters expressed opposition to the current not-prudent circumstance at § 424.12(a)(1)(iii) for areas within the jurisdiction of the United States that are of negligible conservation value for species occurring primarily outside the United States. Commenters stated that there are no provisions in the Act to decline designation of critical habitat in instances where species found primarily outside the United States would have a small conservation impact.

Response: We are retaining this particular provision without revision. The commenters are correct that the Act does not contain a provision for determining that it is not prudent to designate critical habitat for species that occur primarily outside of the United States if a designation would have a negligible conservation impact. Congress did not place a statutory restriction on when the Services could determine that designating critical habitat is not prudent. Instead, Congress left discretion to the Secretaries of Commerce and the Interior to determine the circumstances when designating critical habitat may not be prudent. In our 2016 regulations (81 FR 7414, February 11, 2016), we noted in the preamble that the consideration of whether areas within U.S. jurisdiction provide conservation value to a species that occurs in areas primarily outside U.S. jurisdiction could be a basis for determining that critical habitat designation would not be prudent (81 FR 7414 at 7432, February 11, 2016). As stated in our 2019 regulation (84 FR 45020 at 45041, August 27, 2019), the dictionary defines ''negligible'' to mean ''so small or unimportant as to be not worth considering; insignificant.'' In the context of ''negligible conservation value'' we mean that the conservation value of habitats under U.S. jurisdiction would be insignificant to the conservation of the listed entity, and designation of critical habitat would not be prudent.

For the purposes of clarity and transparency, we added this consideration directly to the regulatory text in our 2019 rule (84 FR 45020 at 45053, August 27, 2019), and for the same reasons we continue to conclude that this provision adds clarity without precluding the authority to designate critical habitat where appropriate. We will make case-specific determinations, based on the best scientific data available, regarding whether critical habitat designations would provide negligible conservation value for particular species that primarily occur outside of U.S. jurisdiction.

Comment 49: Commenters suggested that the current not-prudent circumstance at § 424.12(a)(1)(iv) (where no areas meet the definition of critical habitat) is superfluous because if no areas meet the definition of critical habitat, none would be proposed as critical habitat anyway.

Response: We are not revising this provision with this rulemaking. These situations will be rare; however, the

Services find value in retaining the current § 424.12(a)(1)(iv) for instances when they do arise, and thus decline to remove it from the regulation.

Comment 50: Some commenters who favor complete rescission of the 2019 rule supported their position by expressing support for the ''not beneficial'' provision from the pre-2019 regulations, under which a not-prudent determination would be appropriate when ''designation of critical habitat would not be beneficial to the species.'' Other commenters cited to critical habitat designations promulgated by the FWS during the late 1990s and early 2000s that suggest critical habitat has little benefit. Commenters used these examples to support their contention that critical habitat should only be designated where there would be a demonstrated conservation benefit to the species.

Response: After considering public comments and our reconsideration under E.O. 13990, we decline to rescind the 2019 rule. By including the ''to the maximum extent prudent'' language, Congress recognized that not all listed species would be conserved by, or benefit from, the designation of critical habitat. However, Congress wrote into the Act the fundamental requirement to designate critical habitat ''to the maximum extent'' while still allowing the ''not prudent'' and ''not determinable'' exceptions.

Congress did not provide specific direction or guidance on when designation of critical habitat would be not prudent. We have come to the conclusion that basing not-prudent determinations on whether particular circumstances are present, rather than on whether a designation would not be ''beneficial,'' provides an interpretation of the Act that is clearer, more transparent, and more straightforward. It also eliminates some confusion reflected in the courts' decisions in *Natural Resources Defense Council* v. *Department of the Interior,* 113 F.3d 1121 (9th Cir. 1997) (''*NRDC*''), and *Conservation Council for Hawaii* v. *Babbitt,* 2 F. Supp. 2d 1280 (D. Haw. 1998) (''*CCH*''). In those decisions, the courts remanded the not-prudent determinations at issue because they found that the FWS had not articulated a rational connection between the facts and the agency's conclusion that designating critical habitat would not be beneficial for the species (*NRDC,* 113 F.3d at 1125–26; *CCH,* 2 F. Supp. 2d at 1288). Although the courts held that FWS had failed to weigh the benefits and risks of designating critical habitat or had failed to consider potential benefits beyond consultation benefits, the courts' reasoning indicates that they found the decisions were based on the insufficiency or absence of any factual analyses of the specific data available. The court in *NRDC* also found that, in implementing the regulations that were in place at the time, FWS had erroneously applied a ''beneficial to most of the species'' standard instead of a ''beneficial to the species'' standard. *NRDC,* 113 F.3d at 1126. Moreover, the decisions' reliance on the legislative-history statements equating ''not prudent'' with ''not beneficial to the species'' is undermined by the fact that ultimately Congress did not choose to include the ''not beneficial to the species'' language as a standard or limitation in the Act. Further, we note that in both decisions the courts seem to have considered principles related to the discretionary process for weighing the impacts of critical habitat designation under section 4(b)(2) of the Act, which do not govern ''not prudent'' determinations. In part, this appears to be due to the courts' interpretations of statements the Services had made regarding their intentions in applying the regulatory provisions (see *NRDC,* 113 F.3d at 1125 (''[T]he Service itself has said that it will forgo habitat designation as a matter of prudence only 'in those cases in which the possible adverse consequences would outweigh the benefits of designation.' 49 FR 38900, 38903.'' (emphasis omitted))). We now take the opportunity to clarify the separate nature of ''not prudent'' determinations and the discretionary analyses that we may elect to take under section 4(b)(2) of the Act. We intend these evaluations to address separate factors. We emphasize that determining that a species falls within one or more of the circumstances identified in the revised regulations does not bring the prudency analysis to an end. As the court holdings in both *NRDC* and *CCH* demonstrate, in determining whether designation of critical habitat is prudent, the Services must take into account the specific factual circumstances at issue for each species (*NRDC,* 113 F.3d at 1125; *CCH,* 2 F. Supp. 2d at 1287–88). However, this does not require the Services to engage in the type of area-by-area weighing process that applies under section 4(b)(2) of the Act.

While the statutory language allows us to forgo designating critical habitat in rare circumstances when designating critical habitat would not contribute to the conservation of the species, the Services recognize the value of critical habitat as an important conservation tool, and we expect to designate it in most cases.

Comment 51: A commenter asserted that critical habitat does not apply to Tribal lands and that, therefore, the Services lack the authority to designate on Tribal lands.

Response: While the Services recognize their responsibilities and commitments under Secretaries' Order 3206 and principles of Tribal sovereignty, the Act does not allow for categorical presumptive exclusion or omission of any areas within the jurisdiction of the United States that meet the definition of critical habitat and otherwise qualify for designation. If we determine that Tribal lands meet the definition of ''critical habitat,'' the Act requires that we identify those lands as meeting the definition. However, it is the longstanding policy of the Services to consider and give great weight to Tribal concerns and always consider excluding Tribal lands under section 4(b)(2) of the Act (81 FR 7226, at 7230–7231, February 11, 2016).

Comments on Designation of Unoccupied Critical Habitat

Comment 52: Multiple commenters stated they opposed the proposed revisions to the regulation addressing the designation of unoccupied critical habitat at 50 CFR 424.12(b)(2) because they exceed the Services' legal authorities. Commenters asserted that the 2019 regulatory revisions conformed to the ESA, its legislative history, and case law interpreting the Act, while the proposed revisions do not. Some commenters stated that with these proposed regulatory changes, the Services are claiming the regulatory authority to designate large areas presently unoccupied by an ESA-listed species, even if those areas are not necessary for, do not contribute to, or may never contribute to the conservation of the species; do not contain an essential conservation feature for the species; or are not based on the best scientific data available. One commenter stated that this kind of broad and unfettered discretion triggers heightened scrutiny under the ''major questions doctrine.''

Response: The revisions that we proposed to 50 CFR 424.12(b)(2) and are now finalizing in this rule are consistent with the ESA, its legislative history, and the applicable case law. While the revisions do remove certain criteria for designating unoccupied areas as critical habitat, they do not expand the Services' authorities for designating unoccupied habitat as critical habitat. The revisions remove the requirement that the unoccupied areas have a

''reasonable certainty'' both to contribute to the species conservation and to contain one or more features essential to the species' conservation. These changes also remove the requirement to designate all possible occupied areas as critical habitat before allowing the Services to even consider designating any unoccupied areas. As we discussed in the proposed rule and further in other responses to comments below in this document, these added criteria, most of which were newly added to the regulations in 2019, imposed requirements that go beyond the statutory standards requiring a science-based finding that an unoccupied area is ''essential for the conservation'' of the listed species. We recognize that some commenters consider these now-removed criteria to have provided the Services with reasonable guidance for determining whether certain areas qualify as being ''essential for conservation''; however, we no longer agree. We now find that the criteria could undermine our duty to designate areas that otherwise meet the definition of critical habitat and are essential to support the conservation of the species. In addition, instead of providing a useful interpretation of the Act, those criteria created the perception that, rather than abide by the statutory requirement to base critical habitat designations on the best scientific data available, the Services would need to provide some heightened level of certainty with respect to those data and the areas being designated. Furthermore, as we stated in the proposed rule, imposing a ''reasonable certainty'' standard is also unnecessary in light of the best-available-data standard of the Act, because this standard already prohibits the Services from basing their decisions on speculation.

By removing requirements established under the 2019 regulations, these revisions may allow for designations of unoccupied areas that would have been ineligible for designation under the 2019 regulations. However, because revisions to 50 CFR 424.12(b)(2) do not weaken or undermine the requirements set forth in the ESA for defining critical habitat, they do not allow for expanded or larger designations of unoccupied areas than is permitted under the ESA. As discussed in the proposed rule and further in responses to comments below, we find these revisions appropriate and necessary. The Services must still apply the best available scientific data, and for any critical habitat rulemaking that includes a designation of unoccupied areas, they must explain why the unoccupied areas are ''essential'' for that species' conservation based on a supporting record. These standards prevent the Services from designating large areas of unoccupied habitat that do not meet the statutory requirements for critical habitat.

In short, the revisions to 50 CFR 424.12(b)(2) do not expand our authorities under the ESA, because they do not remove, undermine, or in any way weaken the existing statutory requirements to base critical habitat designations on the best scientific data available, consider potential impacts of designating areas, and make a finding that the unoccupied areas are essential for that species' conservation. The Services have no intention to exceed our authority under the Act by designating ''large'' areas of unoccupied habitat that are not essential for the conservation of the species. Since this regulation directly corresponds to specific authorities granted to the Services under the ESA, the major questions doctrine is not implicated. As further explained below under our response to *Comment 86,* nothing in this rule, including the revisions to 50 CFR 424.12(b)(2), is inconsistent with, or extends beyond, the statutory authority expressly granted to the Services by the Act.

We provide further discussion of the unoccupied critical habitat regulation below in our responses to other related comments (*e.g.,* see also responses to *Comment 61* and *Comment 62,* below).

Comment 53: Several commenters stated we should retain the existing regulation at 50 CFR 424.12(b)(2) because it provides an analytical process by which unoccupied critical habitat will be designated and thus regulatory certainty for stakeholders. Commenters stated the proposed regulation for designating unoccupied critical habitat should provide guidance regarding when an unoccupied area may be considered for designation as critical habitat, rather than simply repeating the statutory language.

Response: Although the 2019 regulation did provide more requirements with respect to designating unoccupied critical habitat, it did not provide greater regulatory certainty to stakeholders or private landowners. The requirement to designate critical habitat under the ESA is directly tied to a species' listing and to any petitions requesting that the Services revise critical habitat. Whether and where critical habitat is ultimately designated depends on what petitions are considered, what species are listed, the particular life history of the species, and the best available data about the species' habitat. As the Services cannot control or readily predict these series of facts and information, there is little in the way of regulatory certainty that can be achieved through general implementing regulations. Determinations of whether a particular unoccupied area of habitat qualifies as critical habitat for a species are fact-specific and depend upon the scientific understanding of the particular species' habitat and conservation needs, which vary tremendously across species and must be addressed within each individual critical habitat rulemaking. The revisions we are finalizing in this rule do not change this practical reality.

Comment 54: Several commenters asserted that the proposed changes to 50 CFR 424.12(b)(2) would put unnecessary and unreasonable economic burdens and costs on local development and industries. The commenters stated the proposed revisions would result in increased land-use restrictions, reduced land values, or other economic impacts, with little conservation benefit.

Response: We recognize and understand the concerns of these commenters; however, as we discuss in our response to *Comment 52,* the revised critical habitat regulation at 50 CFR 424.12(b)(2) does not authorize or direct the Services to designate more or larger areas of unoccupied critical habitat. Therefore, there is no basis to conclude that this regulation will increase economic or other impacts of critical habitat designations. The Services must still adhere to the requirements of the ESA when designating areas as critical habitat. These requirements include the mandatory consideration of economic, national security, and other relevant impacts of designating any particular area as critical habitat under section 4(b)(2) of the ESA, which also permits the Services to exclude particular areas from a designation if the benefits of that exclusion outweigh the benefits of designation. Section 4(b)(2) of the ESA is the appropriate mechanism for considering the type of impacts described by these commenters; purposely constraining what and how areas may even be considered for designation as critical habitat through implementing regulations is not. We also note that because the direct regulatory effect of critical habitat is on Federal agencies and Federal actions, costs associated with conducting additional analyses under section 7 of the ESA are typically born by the Federal action agencies, not by private landowners, small businesses, or industry. Only in instances where a Federal action would result in

destruction or adverse modification of the critical habitat would economic impacts stemming from project modifications actually arise. As the record for both Services indicates, such instances are rare (Macolm and Li 2015; *https://www.regulations.gov/document/FWS-HQ-ES-2018-0009-64309*). Evidence to support assertions that property values invariably decrease as a consequence of the area being designated as critical habitat is equivocal at best (Mamun et al. 2022 IEc 2023; Auffhammer et al. in prep). And while research specifically assessing the economic impacts of critical habitat on land values has to date been limited, there is an extensive body of economic literature indicating that there are often economic benefits (*e.g.,* increased land value, increased home sale price) associated with land conservation (*e.g.,* Bolitzer and Netusil 2000; Curran 2001; MacConnell and Walls 2005; Black 2018).

Comment 55: Some commenters expressed concerns that the proposed revisions to the 2019 regulations for designating unoccupied critical habitat could allow for over-designation of critical habitat, which could in turn undermine land-management activities (*e.g.,* tree thinning to reduce wildfire risk) or negatively affect cooperative conservation and recovery efforts with private landowners. A commenter noted that those impacts could also undercut the goals of E.O. 13990, ''Protecting Public Health and the Environment and Restoring Science To Tackle the Climate Crisis,'' which is a key justification of this current rulemaking. Another commenter urged the Services to consider whether the proposed revisions to the critical habitat regulations, and their potential impacts on private landowners, would help or hamper conservation and recovery efforts.

Response: Although we appreciate the concerns of these commenters, the revised regulation at 50 CFR 424.12(b)(2) that we are finalizing in this rule will not change the extent to which critical habitat designations may impact ongoing management and conservation activities. As discussed in our prior response, while the revised regulations may potentially result in designation of different specific areas as critical habitat, there is no basis to conclude that this regulation will increase the size of areas designated as critical habitat. Under section 4(b)(2) of the ESA, we are required to take into consideration economic, national security, and other relevant impacts of designating any particular area as critical habitat. As part of that analysis, and as reflected in the Services' joint policy on implementing section 4(b)(2) of the ESA (''section 4(b)(2) policy'' 81 FR 7226, February 11, 2016), we evaluate the impact of designation on conservation plans and agreements, as well as on their attendant partnerships. As expressed in our section 4(b)(2) policy, it is our intention to encourage and foster conservation partnerships. In the Services' experience, excluding from a critical habitat designation areas that are covered by existing plans and programs can encourage other land managers to partner with the Services in the future by removing any real or perceived disincentives for engaging in conservation activities. We will continue to apply the section 4(b)(2) policy in the same manner under the revised critical habitat regulation.

With respect to ongoing land-management activities, if those activities involve a Federal agency action, such as permitting or funding, and if they may affect designated critical habitat, then those activities would be subject to the consultation requirements of section 7(a)(2) of the ESA. That statutory requirement is unaffected by the critical habitat implementing regulation we are finalizing in this rule. The outcome of any specific consultation is driven by the particular Federal action and effects of that action on the critical habitat. Thus, there is no basis to conclude that any land management activities would be affected any differently as a result of this rule. Furthermore, as stated previously, while the revised regulation may potentially alter which specific areas are ultimately designated as critical habitat, there is no basis to conclude that critical habitat designations will be larger or include more areas. Consequently, there is no basis to conclude that these revised regulations will result in an increased impact on land management activities or hamper conservation and recovery efforts.

Comment 56: One commenter stated the proposed text for 50 CFR 424.12(b)(2) was too long and the steps for designating unoccupied critical habitat were not in logical order. Another commenter asserted the proposed revisions also removed the ''essential'' criterion from 50 CFR 424.12(b)(2), which is clearly required by the Act. Another stated the proposed changes were overly complicated and that the implications of the proposed changes were hard to understand.

Response: We considered these comments and concluded that no further changes are necessary to improve the logical ordering or length of the proposed text for 50 CFR 424.12(b)(2); thus, we are finalizing the text as proposed. As revised, the regulation is shorter and contains fewer elements than the 2019 regulation and still indicates that unoccupied areas must be ''essential for the conservation of the species,'' which is clearly required by the Act. In this rule, we have included explanations, both generally in the preamble as well as in responses to specific comments, of the intent, meaning, and implications of this particular revision. As we discuss in response to other specific comments on this particular provision, the revised regulation at 50 CFR 424.12(b)(2) does not expand the Services' authorities beyond the limits established by the Act, nor will it necessarily lead to larger or more expansive designation of unoccupied critical habitat.

Comment 57: Several commenters stated that, as written, the proposed text of 50 CFR 424.12(b)(2) would require the Secretary to identify critical habitat outside the area occupied by the species at the time of listing or appears to mandate the designation of unoccupied critical habitat. Commenters stated the proposed revision fails to acknowledge that the Services have the option not to designate unoccupied areas. One commenter requested we reword this provision to indicate that there may not be unoccupied areas that are essential to conservation.

Response: We considered these comments and concluded that rewording of the proposed 50 CFR 424.12(b)(2) is not necessary because the regulation does not indicate or imply that designation of unoccupied areas of critical habitat is required. The text of the regulation uses the same phrasing as the other provisions set forth at 50 CFR 424.12(b)—*i.e.,* ''the Secretary will identify''—and lays out only the process and requirements for identifying areas ''to be considered for designation as critical habitat'' (see 50 CFR 424.12(b)). The regulation does not state that such areas will or must be designated as critical habitat. This section of the regulations purposely does not refer to designation because, as indicated in subsequent sections of the regulations, there are additional requirements that must be met prior to proposing or finalizing a critical habitat designation. The Services could also still consider excluding particular areas from a designation after considering the economic, national security, and other relevant impacts of designating those areas as critical habitat (see 16 U.S.C. 1533(b)(2), 50 CFR 424.19). Furthermore, unoccupied areas may only be designated if they meet the statutory requirement that they are

essential for the species' conservation, and the text of 50 CFR 424.12(b)(2) in no way mandates such a finding.

Comment 58: A commenter indicated they support the proposed changes to the unoccupied critical habitat regulation, but also requested that the Services use a Solicitor's M-Opinion for determining and describing the process for designating unoccupied critical habitat. This commenter stated such an opinion could provide an extensive evaluation of the legislative and judicial history, a description of the complex framework or process that the Services would implement, and examples of how it may be applied. The commenter asserted this opinion would serve as a publicly available standard reference document that could reduce the likelihood of successful challenges in court.

Response: We appreciate this commenter's suggestion regarding development of additional, publicly available guidance regarding the designation of critical habitat, but we do not think such a document is necessary at this time. The Services strive to provide clear, transparent, and accessible information to the public whenever possible so that interested and affected parties can more readily understand the legal framework, legal and technical terms and standards, and procedural requirements associated with mandated duties and obligations under the ESA. In addition to the joint implementing regulations at 40 CFR part 424 and the Services' section 4(b)(2) policy, each agency provides additional information and resources regarding critical habitat on their respective websites (see *https://www.fisheries.noaa.gov/national/endangered-species-conservation/critical-habitat* and *https://www.fws.gov/project/critical-habitat*), and every critical habitat rule provides a detailed explanation of the processes, analyses, and legal support that underlie that rule.

Comment 59: Numerous commenters stated they support the proposed changes to 50 CFR 424.12(b)(2), which they stated better reflect both the Act and the legislative history. Several commenters stated that unoccupied habitat is sometimes essential to successfully recovering a species, and when the best available science includes information regarding the future habitat needs of a species, those areas should be considered for critical habitat designation. Some commenters stated the proposed changes would ensure that habitat protections will be determined using the best available scientific data, and other commenters noted the revisions are especially important for endangered and threatened species with habitats that are being impacted by climate change. Some commenters stated that the unnecessarily high standards for designating unoccupied critical habitat established by the 2019 regulation were in conflict with the ESA and could negatively impact future recovery efforts. Several commenters stated that the proposed changes are consistent with and would better support the ESA's goal of conserving ecosystems upon which endangered and threatened species depend.

Response: We appreciate and agree with the comments in support of the proposed rule.

Comment 60: Multiple commenters stated they support the proposed removal of the strict sequencing requirement at 50 CFR 424.12(b)(2), and some noted the proposed softening of this requirement follows good conservation practice. Other commenters noted they agreed that the Services should not be required to exhaust all possible occupied areas before being able to consider designating unoccupied areas as critical habitat. Several commenters, however, recommended this text be further revised to indicate that the Services can consider occupied and unoccupied areas simultaneously for possible designation as critical habitat, or return to the 2016 version of this regulation, which did not include a two-step process for determining critical habitat. One of these commenters stated that the two-step process included in the proposed rule creates unnecessary barriers to designation, leads to less-effective conservation, and incorrectly implies that unoccupied areas are less important to a species' survival and recovery.

Response: We appreciate and agree that unoccupied areas of critical habitat may be just as important for a species' conservation as the areas where the species was known to occur at the time of listing under the ESA. We also recognize that, especially in light of climate change and associated shifts from historical habitats into new areas, unoccupied habitats may become increasingly important for species conservation efforts in the future. We do not agree, however, that the continued focus on occupied areas, and the approach of identifying occupied areas first, will impede the Services' ability to designate critical habitat in a way that effectively supports species' survival and recovery. As mentioned previously, it has been our longstanding practice to begin our assessments of potential critical habitat by evaluating the areas that the species currently occupies. Understanding how the species is currently distributed and using available habitat helps support our analysis of whether additional, unoccupied areas are needed to support the species' conservation. We do not view the unoccupied areas as necessarily less important, but those areas should be considered carefully and in light of what we know about the species' habitat needs and its occupied habitats. Therefore, we are finalizing this regulation as proposed.

Comment 61: Many commenters requested we retain the requirement at 50 CFR 424.12(b)(2) that the Services must first determine that occupied critical habitat is inadequate to conserve the species before we can consider whether any unoccupied areas are essential for the species conservation—either by retaining the 2019 regulation or by making additional revisions. Multiple commenters stated the ''sequencing'' or prioritization approach in the 2019 regulations is a reasonable, or even a necessary, analytical framework for assessing whether unoccupied areas are essential for the species because as a matter of logic, an unoccupied area cannot be considered ''essential for the conservation'' of a species if the occupied areas are adequate to ensure its conservation. Some commenters asserted that the courts, the Services' decades-old regulations, and fundamental logic all indicate that it is not possible to conclude that an unoccupied area is essential for the conservation of a species without knowing how the species would fare if the unoccupied area were not designated.

Response: We do not agree that the inflexible approach established in the 2019 regulations regarding unoccupied critical habitat was the best or a necessary one. The revisions we are making to 50 CFR 424.12(b)(2) do not necessarily conflict with the logic expressed by the commenters, as we are simply removing the rigid requirement to exhaustively designate all occupied areas of critical habitat before we can even consider whether any unoccupied areas are essential for the species' conservation. As we have stated previously, a rigid step-wise approach (*i.e.,* ''exhausting'' the occupied critical habitat, and then designating essential unoccupied habitat only if the occupied critical habitat is not enough to support the species' conservation) does not necessarily support the best conservation strategy for all species and could even result in a designation that is both geographically larger and potentially less effective as a

conservation tool. By removing this rigid ''sequencing'' or ''exhaustion'' requirement, the Services can instead consider the inclusion of occupied and unoccupied areas in a critical habitat designation in a manner that best supports the conservation needs of the species, while also allowing for exclusions of particular areas where appropriate under section 4(b)(2) of the ESA. Thus, removal of the ''exhaustion'' requirement ensures that the Services have the flexibility that is already authorized under the ESA to evaluate unoccupied areas that are ''essential for conservation'' based on the best scientific data available without first being required to designate all occupied areas of critical habitat.

As discussed by some commenters, the 2019 regulation was not the first time the Services' implementing regulations contained a two-step or exhaustion approach for designating occupied and unoccupied critical habitat; the implementing regulations took this approach from 1980 to and 2016 (''pre-2016 regulation''), and from 2019 to the present (see 45 FR 13010, February 27, 1980; 49 FR 38900, October 1, 1984; 81 FR 7414, February 11, 2016; 84 FR 45020, August 27, 2019). As with the 2019 regulation, the pre-2016 regulation prioritized the designation of occupied areas over unoccupied areas by allowing the Services to designate unoccupied areas as critical habitat only if a critical habitat designation limited to occupied areas would be inadequate to ensure the conservation of the species (49 FR 38900 at 38909, October 1, 1984; 84 FR 45020 at 45053, August 27, 2019). This version of the regulations suffered from the same issue as the 2019 regulations—the possibility of being interpreted as saying that, to designate unoccupied critical habitat, we must designate all of the occupied areas that we could possibly designate because they meet the definition of occupied critical habitat and then determine that the designation would be inadequate to provide for the conservation of the species.

In 2016, we removed the two-step requirement entirely from the implementing regulations, stating that it was an unnecessary and unintentionally limiting requirement (81 FR 7414 at 7434, February 11, 2016), and we revised the regulation to instead allow for simultaneous consideration of occupied and unoccupied areas. When we then reinstated the two-step ''sequencing'' or ''exhaustion'' prioritization process in 2019, we explained that we were responding to concerns that the Services would inappropriately designate overly expansive areas of unoccupied critical habitat (see 83 FR 35193 at 35197–98, July 25, 2018), and that a two-step approach would help further Congress's intent to place increased importance on habitat within the geographical area occupied by the species (84 FR 45020 at 45043, August 27, 2019).

We now recognize that we can retain a two-step approach and maintain an emphasis on occupied areas without imposing a rigid limitation upon the Services' ability to designate unoccupied critical habitat that is nowhere set forth in the statute itself. Thus, the version of the regulation we are finalizing in this rule indicates that the Services will first identify ''areas occupied by the species''; however, as already noted, the regulation also allows the Services the flexibility to identify unoccupied areas that are essential for the species' conservation based on the best scientific data available—the statutory standard—without requiring that the Services first exhaust all occupied habitat—a limitation without a clear statutory basis. This flexibility was lacking in both the pre-2016 and the 2019 regulations. The revised regulation provides a different and reasonable approach for emphasizing occupied areas in a way that does not suggest an ''exhaustion'' requirement or unnecessarily constrain the Services' ability to designate unoccupied areas that are essential for the species.

The approach we are finalizing in this rule is also not inconsistent with case law cited by the commenters that interpreted the pre-2016 regulations. While various court rulings provided some insight with respect to the issue of ''sequencing'' and emphasizing occupied critical habitat, none indicated there is a statutory obligation to exhaustively designate all occupied areas before designating any unoccupied areas. Likewise, no court has ruled that under the Act, before designating unoccupied critical habitat, the Services must first determine that designating all of the occupied critical habitat would be ''inadequate'' and, therefore, that the Services *must exhaust designating all* potential areas of occupied habitat before the Services can determine that unoccupied areas are essential for a species' conservation. Instead, these courts held that the Services' regulatory interpretation at the time merely elaborated the statutory standard requiring that, for unoccupied areas to meet the definition of ''critical habitat,'' they must be essential for the conservation of the species (*Bear Valley Mut. Water Co.* v. *Jewell,* 790 F.3d 977, 994 (9th Cir. 2015); *accord N.M. Farm & Livestock Bureau* v. *U.S. Dep't of Interior,* 952 F.3d 1216, 1231 (10th Cir. 2020)). Neither the Act nor applicable case law contains a requirement to exhaust designating all occupied critical habitat before designating unoccupied critical habitat.

Comment 62: A number of commenters viewed the proposed regulatory requirements for designating unoccupied critical habitat as being unlawful and inconsistent with the ESA, existing case law, and the legislative history related to the 1978 and 1982 amendments to the ESA. Commenters stated that the two-part statutory definition in the ESA effectively creates a two-part regulatory hierarchy that prioritizes occupied areas over unoccupied areas, noting that the legislative history indicates that the Services must be ''exceedingly circumspect'' when designating unoccupied critical habitat (H.R. 96–1625 at 25 (1978)), and designation of unoccupied areas should be more onerous. Some commenters also pointed to various court rulings, including the Supreme Court ruling in *Weyerhaeuser Co.* v. *U.S. Fish & Wildlife Serv.,* 139 S. Ct. 361, 368–69 (2018) (hereafter, *Weyerhaeuser*), in support of their view that unoccupied critical habitat must be absolutely necessary or indispensable for the species' conservation, and, therefore, the Services must first determine that occupied areas are inadequate to conserve the species. Another commenter stated that, while the ESA does not require a finding of inadequacy of the occupied critical habitat to consider unoccupied areas, Congress emphasized the need to focus on occupied areas first.

Response: We agree that both the legislative history surrounding the amendments to the ESA establishing the definition and requirements for critical habitat and the existing case law support a conclusion that the standard for determining whether unoccupied areas qualify as critical habitat is more onerous than the standard for determining whether occupied areas qualify as critical habitat (*e.g., Home Builders Ass'n* v. *U.S. Fish & Wildlife Serv.,* 616 F.3d 983, 990 (9th Cir. 2010) (''Essential for conservation is the standard for unoccupied habitat . . . and is a more demanding standard than that of occupied critical habitat.''); *Cape Hatteras Access Pres. All.* v. *U.S. Dep't of Interior,* 344 F. Supp. 2d 108, 119 (D.D.C. 2004) (''[W]ith unoccupied areas, it is not enough that the area's features be essential to conservation, the area itself must be essential''); S. Rep. No. 95–874, at 9–10 (1978)). We also are aware of and considered the legislative

history that many commenters cited in support of their view that designation of unoccupied critical habitat is supposed to meet a higher or more onerous test (*e.g.,* H.R. Rep. No. 95–1625, at 742 (1978) (''[T]he Secretary should be exceedingly circumspect in the designation of critical habitat outside of the presently occupied area of the species'')), and we do not take issue with the statement or idea that the Services should be exceedingly circumspect when designating unoccupied areas as critical habitat.

However, none of these sources establishes a legal basis for requiring that the standard for determining whether any unoccupied area meets the definition of ''critical habitat'' must go beyond the standard provided by the ESA. In defining ''critical habitat'' in section 3 of the ESA, Congress established the two different standards for determining whether an area is critical habitat, depending on whether that area is occupied by the species at the time of its listing or not occupied by the species at the time of its listing. Those differing standards are how Congress chose to express its view that the two types of areas should be assessed and treated differently. The statutory definition provides the only test that the Services must meet to designate an area as critical habitat. By revising the regulations at 50 CFR 424.12(b)(2) to correspond more closely to the statutory definition of ''critical habitat,'' and eliminating requirements in the 2019 regulations that go beyond those of the Act, we are adhering to intent and direction of Congress.

Comment 63: Some commenters stated that the proposed removal of the sequencing requirement at 50 CFR 424.12(b)(2) was not adequately justified, and that because this was such a long-held interpretation, the rationale that the proposed revisions provide a better interpretation of the congressional intent is not plausible. Another commenter stated that the proposed removal of the sequencing requirement was poorly supported in part because the Services did not provide any examples of how this requirement has constrained our ability to designate unoccupied critical habitat.

Response: As we discussed in the proposed rule (88 FR 40764, June 22, 2023), we are revising the regulations regarding the designation of unoccupied critical habitat to remove requirements that are not mandated by the language or structure of the ESA and, in the view of the Services, to better fulfill the Secretaries' authority to further the conservation purposes of the ESA. By removing the rigid ''sequencing'' requirement, the Services can continue to prioritize our consideration of occupied areas but still consider the inclusion of occupied and unoccupied areas in a critical habitat designation without having to exhaust all areas of occupied critical habitat first. We find that this approach is more faithful to the statutory definition of ''critical habitat'' and will allow the Services necessary flexibility to apply the best scientific data available to designate critical habitat in a manner that best supports the conservation needs of the species. We also find this revision is consistent with E.O. 13990's policy of improving protections to the environment. Rather than taking a ''wait-and-see'' approach to determine whether these identified issues with the 2019 rule would manifest in specific critical habitat designations, we are making this revision proactively.

Comment 64: Some commenters objected to the proposed removal of the requirement to first determine that occupied areas are ''inadequate'' because they are concerned it would allow for arbitrary or overly expansive or vast critical habitat designations. Commenters stated that there is no indication that Congress intended critical habitat to include large tracts of unoccupied lands for population expansion. Some commenters asserted that by linking critical habitat to the listing process and not delaying it until a recovery strategy was developed, Congress clearly intended that designation of unoccupied critical habitat should be limited to areas needed for the species' survival and should not include areas for population expansion or recovery.

Response: We do not agree that the regulation regarding unoccupied critical habitat that we proposed on June 22, 2023, and are finalizing in this rule will lead to arbitrary or overly large designations. While the changes we are finalizing do remove certain constraints for designating unoccupied areas as critical habitat, these changes do not expand the Services' authorities under the ESA. The Services must still base critical habitat designations on the best scientific data available and can only designate unoccupied areas if the data support a conclusion that those areas are essential for that species' recovery. Nothing in this rule undermines or weakens those foundational, statutory requirements.

Despite some concerns expressed in the legislative history (*e.g.,* S. Rep. No. 95–874, p. 10 (May 15, 1978)), we do not agree with the comments stating or implying that Congress intended critical habitat designations to be limited to only the areas needed for a species' survival. The plain language of the ESA indicates this is not a correct interpretation, as the definition of ''critical habitat'' refers specifically to ''conservation'' and not ''survival.'' In defining the terms ''conserve, conserving, and conservation'' in section 3 of the ESA, Congress made it clear that the term ''conservation'' refers to all actions needed to bring the species to the point at which protections provided under the ESA are no longer necessary. We cannot substitute the term ''survival'' and its meaning in place of the term ''conservation'' and its meaning when reading and interpreting the statutory definition of critical habitat. Applicable case law has also consistently supported the view that critical habitat is habitat necessary for both survival and recovery of the listed species (see *Gifford Pinchot Task Force* v. *U.S. Fish & Wildlife Serv.,* 378 F.3d 1059, 1070 (9th Cir. 2004) (''Clearly, then, the purpose of establishing 'critical habitat' is for the government to carve out territory that is not only necessary for the species' survival but also essential for the species' recovery.''); *Sierra Club* v. *U.S. Fish & Wildlife Serv.,* 245 F.3d 434, 442 (5th Cir. 2001) (noting that the ESA's definition of critical habitat ''is grounded in the concept of 'conservation'''); *Center for Biological Diversity, Defenders of Wildlife* v. *Kelly,* 93 F. Supp. 3d 1193, 1201 (D. Idaho 2015) (noting that critical habitat is ''defined and designated 'in relation to areas necessary for the conservation of the species, not merely to ensure its survival.''' (quoting *Ariz. Cattle Growers' Ass'n* v. *Salazar,* 606 F.3d 1160, 1166 (9th Cir. 2010); *Alaska Oil & Gas Ass'n* v. *Jewell,* 815 F.3d 544, 555–56 (9th Cir. 2016))).

Comment 65: Some commenters stated that the proposed elimination of the sequencing requirement could lead to increased conflict, controversy, and litigation, because the Services would have to rely on their expertise and their ability to adequately explain the scientific basis for when unoccupied habitat is deemed nonessential. As evidence of such controversy, some commenters pointed to the recent Supreme Court decision in *Weyerhaeuser,* in which unoccupied critical habitat for the dusky gopher frog was contested by the private property owner. The commenters also suggested that designation of unoccupied critical habitat could undermine conservation and lead to perverse incentives for landowners to destroy habitat before it becomes occupied by the listed species.

The commenter suggested the Services focus on areas where a critical habitat designation will encourage conservation.

Response: We do not agree that the changes we are now making to the implementing regulations regarding the designation of unoccupied areas of critical habitat will lead to increased conflict, litigation, or controversy over critical habitat designations. Even with the changes we are making in this rule, the Act will still require that we designate critical habitat on the basis of the best scientific data available. Despite their limited regulatory effect (*i.e.,* through the ESA section 7(a)(2) requirement that Federal agencies ensure their actions are not likely to destroy or adversely modify critical habitats), critical habitat designations are consistently one of the most controversial protections afforded listed species under the ESA. It has been the experience of both Services that controversy related to critical habitat designations depends more on factors such as the size and location of the designation rather than whether the areas being designated are occupied or unoccupied.

The revisions we are making to 50 CFR 424.12(b)(2) do not alter the Services' longstanding practice of first considering areas within the geographical area occupied by the species when developing a critical habitat designation. As reflected in the first sentence of this revised regulation, the Services will still consider and identify occupied areas first before assessing whether any unoccupied areas are essential for the species' conservation. We find that this approach is the most logical way to begin a critical habitat analysis and has consistently been the practice of the Services regardless of which regulations have been in place. The revisions we are making thus do not completely remove the prioritization of occupied areas over unoccupied areas; they instead remove the requirement that the Services exhaust all occupied areas before considering whether any unoccupied areas may be essential for conservation of the particular species.

As the critical habitat at issue in *Weyerhaeuser* was designated under the pre-2016 regulations (see 77 FR 35118, June 12, 2012), which included a two-step or ''sequencing'' requirement, this example does not support the assertion that elimination of a ''sequencing'' requirement will increase litigation or controversy. Instead, the *Weyerhaeuser* example aligns with our expectation that removal of the strict sequencing step will have no effect on the level of controversy associated with designations of unoccupied critical habitat, which in our experience is largely driven by where the critical habitat is located (*e.g.,* on private lands) and its size.

The ESA allows for consideration of the potential impacts on conservation efforts when designating critical habitat, and as described in the Services' section 4(b)(2) policy (81 FR 7226, February 11, 2016), we will consider areas covered by conservation agreements or plans when assessing the benefits of including and excluding particular areas from a designation. In particular, the Services consider whether such conservation plans are already providing on-the-ground conservation that would reduce the benefit of designating the same area as critical habitat. We expect that our approach of examining whether to exclude from designation areas that are subject to voluntary conservation agreements and plans will continue to provide a substantial incentive to private landowners and help further the conservation of listed species while also minimizing regulatory impacts. This approach is also consistent with our authorities and the intent of section 4(b)(2) of the ESA.

With respect to the perverse incentives described by the commenter, we do not agree that the revisions we are making to 50 CFR 424.12(b)(2) in this rule will alter those behaviors or attitudes. To the extent that any perverse incentives exist with regard to modifying habitat conditions on private lands, it has been the Services' experience that these attitudes persist regardless of any specific regulation. We are also aware that deliberate modification of areas to make private property less hospitable to listed species may have occurred previously in response to species' listings under the ESA rather than in response to, or in potential avoidance of, a critical habitat designation.

Comment 66: A commenter recommended that, if we finalize the proposed removal of the sequencing requirement at 50 CFR 424.12(b)(2), the final rule should indicate that the Services will identify unoccupied privately owned areas in recovery plans versus critical habitat rules due to the controversy associated with designating such areas. The commenter stated that recovery plans, which have overlapping but broader goals than critical habitat designation, are the appropriate place to consider such lands, especially given that the areas do not provide immediate habitat for the listed species, and this approach would reduce controversy and maintain the focus on collaboration.

Response: We appreciate the suggestion to use recovery plans as a means to identify unoccupied areas of critical habitat. However, the ESA requires the Services to designate critical habitat concurrently with listing or, if not yet determinable, within 1 year from the date of listing. Recovery plans are developed after a species is listed, typically involve coordination with multiple partners and stakeholders, and require a period of public review before being finalized. As a result, recovery plans are often finalized well after the species is listed under the ESA. The ESA does not allow us to delay designating critical habitat until such time as a recovery plan is completed, nor does it allow the Services to exempt private lands from a critical habitat designation and instead identify those lands as essential for a species' conservation in a recovery plan. Moreover, courts have noted that the recovery plan's requirements are separate and distinct from critical habitat designation. (See generally *N.M. Farm & Livestock Bureau* v. *U.S. FWS,* 952 F.3d 1216, 1232–33 (10th Cir. 2020) (recovery plan provision ''is entirely separate from the requirements for the designation of critical habitat''); *Home Builders Ass'n of N. Cal.* v. *U.S. FWS,* 616 F.3d 983, 989–990 (9th Cir. 2010) (distinguishing recovery plan and critical habitat designation requirements)). We decline to adopt regulatory provisions that would blur the distinct statutory requirements established by Congress for critical habitat designation and recovery planning.

Comment 67: Several commenters stated they support the proposed removal of the requirement for unoccupied areas to contain essential features, because there is no legal basis for such a requirement or such a requirement is in direct conflict with the ESA.

Response: We appreciate the commenters' support of our proposed changes.

Comment 68: A number of commenters opposed the proposed removal of the requirement for unoccupied areas to contain one or more essential features and stated that this requirement is a logical way to establish that an area is habitat for the species. Some commenters stated that an area cannot be habitat for a species if it does not contain at least one feature necessary for the existence and survival of a species, and to comply with the Supreme Court's ruling in *Weyerhaeuser,* an area must be habitat for a species to be considered critical habitat. Other commenters stated the

proposed revisions ignore, downplay, or are inconsistent with the *Weyerhaeuser* ruling, and that to ensure consistency with the *Weyerhaeuser* ruling, the regulation should be rephrased to indicate that the unoccupied areas under consideration are habitat or rephrased to specifically require that the area is presently capable of supporting one or more life processes of the species. Some commenters asserted that removal of the essential-feature requirement indicates the Services will not apply a sufficient scientific rationale when determining which unoccupied areas are essential for a species' conservation, or that the Services will designate areas that are not habitat for the species.

Response: We understand the commenters' concerns and desire for assurances that critical habitat will be designated in a manner consistent with the Supreme Court's ruling in *Weyerhaeuser.* As we have stated previously, we recognize the importance of the Supreme Court's ruling in *Weyerhaeuser,* and we intend to designate critical habitat in a manner consistent with that ruling (87 FR 37757, June 24, 2022; 88 FR 40764, June 22, 2023). However, we also now recognize that importing language from the statutory definition of ''occupied'' critical habitat (regarding essential features) into the regulatory requirements for defining ''unoccupied'' critical habitat is not the best way to ensure that unoccupied critical habitat is habitat for the listed species. Congress defined occupied critical habitat and unoccupied critical habitat separately, purposely setting different standards for defining each type of critical habitat and referred to essential features only in connection with occupied critical habitat (see 16 U.S.C. 1532(5)(A)(i)). We now find that when we revised this regulation in 2019, we confounded the criteria for defining occupied and unoccupied critical habitat, and thereby eroded the clear statutory distinction between those two types of areas. In other words, by adding the requirement for unoccupied areas to contain one or more essential features in 2019, we made the standards for designating those areas more similar than what the ESA plainly indicates. The revisions we are finalizing today will realign the implementing regulation at 50 CFR 424.12(b)(2) with the statutory standards for defining and designating unoccupied critical habitat. These revisions avoid the potential for rendering any part of the statutory language surplusage.

In *Weyerhaeuser,* the Court held that an area is eligible for designation as critical habitat under the ESA only if it is habitat for that species. The *Weyerhaeuser* ruling is sufficiently clear on this matter and stands on its own; thus, we find there is no need to build this ruling explicitly into the ESA implementing regulations. The *Weyerhaeuser* decision did not address what should or should not qualify as ''habitat''; thus, it in no way established any requirements regarding presence of essential features or habitability of the area. We find that, rather than creating additional regulatory requirements that confound or go beyond the statutory standards, it is more appropriate to make determinations regarding whether areas qualify as habitat for a given species by applying the best available scientific data, as required by the ESA, and providing clear explanations of those data in each individual critical habitat rule.

Comment 69: Some commenters requested that we clarify the process for determining critical habitat by providing a regulatory definition of the term ''habitat.'' Several commenters stated that the absence of a clear definition of ''habitat'' would lead to regulatory and legal uncertainty, would decrease transparency and predictability, would increase litigation over the definition of ''habitat,'' and could even potentially delay important clean-energy infrastructure projects or result in fewer projects pursued. One commenter stated that the proposed revision of 50 CFR 424.12(b)(2) eliminated the word ''habitat'' and was therefore an attempt to circumvent the Supreme Court's ruling in *Weyerhaeuser.* This commenter stated that in the absence of a regulatory definition of ''habitat,'' the proposed rule used vague and subjective language, such as ''specific areas outside the geographical area occupied by the species at the time of listing.''

Response: The proposed revisions to 50 CFR 424.12(b)(2), which we are finalizing in this rule, are in no way an attempt by the Services to circumvent or disregard the Supreme Court's ruling that to qualify as critical habitat an area must first be habitat for the particular species. The court's ruling did not require that the Services develop a definition of the term ''habitat,'' and we do not agree that a definition is necessary to designate critical habitat in a manner consistent with this ruling (see also our response to *Comment 68*). We also do not agree that the language in 50 CFR 424.12(b)(2) is vague or overly subjective. This language is consistent with the statutory language in 16 U.S.C. 1532(5)(A)(ii), and the particular phrase cited by the commenter (*i.e.,* ''specific areas outside the geographical area occupied by the species at the time of listing'') comes directly from the statutory definition of ''critical habitat.'' Furthermore, the phrase ''geographical area occupied by the species'' has already been defined in the ESA implementing regulations at 50 CFR 424.02.

Through our prior efforts to codify a regulatory definition of ''habitat'' (85 FR 81411, December 16, 2020), we ultimately found that, to encompass the diverse array of species' habitat requirements and simultaneously encompass both occupied and unoccupied critical habitat as defined under the ESA, the resulting regulatory definition of ''habitat'' had to be generic and broad. The resulting definition we developed was neither clear nor sufficiently informative to allow for any conclusions to be reached about whether a particular area would be considered habitat for a particular species (87 FR 37757, June 24, 2022). We also concluded that, given the complexity and variety of factual information pertaining to each individual species that the Services must consider, it is not possible to develop any ''habitat'' definition that would allow for perfect predictability in determining what areas constitute habitat. The public had ample opportunity to comment on both the 2020 habitat definition rule and the 2022 rescission rule. We did not reopen our prior decision to rescind the 2020 definition of ''habitat'' with this rulemaking, as we did not propose a new definition of this term or express a willingness to accept comments on this issue. We find no basis to conclude that a regulatory definition of ''habitat'' would reduce regulatory or legal uncertainty associated with the designation of unoccupied critical habitat, increase transparency and predictability of designations, or affect the timing or number of infrastructure projects. Any necessarily generic definition of this term would also not increase the consistency and transparency in the Services' approach for designating critical habitat designations beyond that already achieved through the existing, governing requirements of the ESA, the implementing regulations, and applicable court decisions.

Comment 70: Several commenters opposed the proposed removal of the requirement that unoccupied areas contain one or more physical or biological features essential to the conservation of the species, stating the current regulation is consistent with the ESA. Commenters asserted that the structure of the ESA's section 3

definition of ''critical habitat'' compels the conclusion that the prerequisite that areas contain ''physical or biological features'' applies to both occupied and unoccupied areas. The commenters stated that if the ESA's less demanding standard for designating ''occupied areas'' requires the presence of ''physical or biological features,'' then the more demanding standard for designating ''unoccupied areas'' must also require the presence of ''physical or biological features.''

Response: As discussed previously, the statutory definition of ''critical habitat'' contains two distinct prongs: one provides the criteria for determining whether ''occupied'' areas qualify as critical habitat (16 U.S.C. 1532(5)(A)(i)), and the second provides the criterion for determining whether ''unoccupied'' areas qualify as critical habitat (16 U.S.C. 1532(5)(A)(ii)). The second prong of the definition in section 3(5)(A)(ii) of the ESA (16 U.S.C. 1532(5)(A)(ii)) states that critical habitat includes specific areas outside the geographical area occupied by the species at the time it is listed under the ESA that the Secretary determines are essential for the conservation of the species. In contrast to section 3(5)(A)(i) (16 U.S.C. 1532(5)(A)(i)), this second prong of the critical habitat definition does not mention physical or biological features, much less require that the specific areas contain the physical or biological features essential to the conservation of the species. This two-prong structure of the definition indicates that Congress intended the two types of critical habitat to have distinct as opposed to the same standards. A regulation requiring unoccupied areas to contain essential features has the effect of making the standards for defining unoccupied critical habitat more similar to those of occupied critical habitat, not ''more demanding.'' As a number of courts have indicated, the higher or more demanding standard for designating unoccupied areas does not stem from whether essential physical or biological features are present, but from whether the area itself is essential for the species' conservation (*Home Builders Ass'n* v. *U.S. Fish & Wildlife Serv.,* 616 F.3d 983, 990 (9th Cir. 2010) (''Essential conservation is the standard for unoccupied habitat . . . and is a more demanding standard than that of occupied critical habitat.''); *Cape Hatteras Access Pres. All.* v. *U.S. Dep't of the Interior,* 344 F. Supp. 2d 108, 119 (D.D.C. 2004) (''[W]ith unoccupied areas, it is not enough that the area's features be essential to conservation, the area itself must be essential'')).

Comment 71: Several commenters stated they opposed removal of the ''essential features'' requirement in 50 CFR 424.12(b)(2) because an area cannot be reasonably construed as ''essential for the conservation of the species'' if the area is uninhabitable by the species and there is no reasonable probability that it will become habitable by the species or that it would have to be substantially altered from its current condition to meet the habitat needs of the species. One commenter stated that, in *Weyerhaeuser,* the Supreme Court explicitly rejected the lower court's conclusion that ''there is no habitability requirement in the text of the ESA or the implementing regulations.'' Commenters also asserted that the legislative history of the 1978 ESA amendments plainly displays Congress's expectation that unoccupied critical habitat encompasses only those areas currently sustaining or currently capable of sustaining species. Several commenters expressed concerns that the proposed revision could or would allow the Services to designate areas that do not have any essential features and then require restoration of the area through section 7 of the ESA and conditioning of Federal permits. One commenter stated that the fact that an area may become habitat at some point in the future does not render it habitat at the time of the critical habitat designation. Several other commenters urged the Services to revise the regulation to at least require a finding that the area will support the essential features in the foreseeable future.

Response: We do not agree that importing a portion of the statutory definition for ''occupied'' critical habitat (*i.e.,* requiring presence of physical or biological features essential to the conservation of the species) into the requirements for determining what areas qualify as ''unoccupied'' critical habitat is the appropriate way to resolve the question of whether an area is habitat for a species. Nor is conflating the definitions of occupied and unoccupied habitat appropriate to resolve whether an area is essential for that species' conservation. We agree that Congress through the statutory text and the Supreme Court in *Weyerhaeuser* provide consistent direction that an area must be habitat for the species in order for it to be designated as critical habitat under the ESA. (See 16 U.S.C. 1533(a)(3)(A)(i), which states that ''[t]he Secretary shall ''. . . designate *any habitat of such species* which is then considered to be critical habitat . . . .'' (emphasis added); and *Weyerhaeuser Co.* v. *U.S. FWS,* 139 S. Ct. 361, 372 (2018) (''Only the 'habitat' of the endangered species is eligible for designation as critical habitat.'')). In *Weyerhaeuser,* the Supreme Court also stated that the statutory definition of ''critical habitat'' is ''no baseline definition of habitat'' and that it ''leaves the larger category of habitat undefined'' (see *Weyerhaeuser Co.* v. *U.S. FWS,* 139 S. Ct. 361, 372 (2018)). When this case reached the Supreme Court, whether the unoccupied area at issue in that case could support the listed species was still in dispute. Neither the Supreme Court nor the lower court ruled on that aspect of the case. The Supreme Court, stating that the lower court had ''no occasion to interpret the term ''habitat'' in section 4(a)(3)[(A)](i) [of the ESA] or to assess the Service's administrative findings'' regarding whether the area in dispute was habitat, remanded the lower court's ruling with instruction to ''consider these questions.'' *Weyerhaeuser Co.,* 139 S. Ct. at 369. As this case was ultimately resolved as a result of revisions by the FWS to the critical habitat designation, the lower court had no further cause to address these questions. In other words, even upon remand, the lower court did not opine on or provide an interpretation of the term ''habitat.'' Therefore, neither this particular case history nor the statutory definition of ''critical habitat'' establishes requirements or guidance with respect to the meaning of the term ''habitat.''

Removal of the ''essential feature requirement'' in 50 CFR 424.12(b)(2) will not alter the need for the Services to abide by both Congress' statutory direction and the Supreme Court's ruling in *Weyerhaeuser* to designate areas that are habitat for the listed species. This revision will also not alter the need for the Services to make the statutorily required finding that an unoccupied area is essential for the conservation of the listed species to designate it as critical habitat. Whether an unoccupied area constitutes habitat and is essential for the conservation of a species will be case- and fact-specific and must be based on the best scientific data available for the listed species. Furthermore, we find it most appropriate and consistent with the conservation purposes of the ESA to consider areas as habitat if they fit within any reasonable biological understanding of ''habitat'' as established by the best available scientific data for a particular species. We also note that neither Congress nor the *Weyerhaeuser* ruling established any prohibition on designating areas as critical habitat if those areas may

require some reasonable restoration to become accessible, habitable, or capable of supporting the species. The Services will not designate areas that are wholly unsuitable for the given listed species or that require extreme intervention or modification to support the species, but it is not necessary or consistent with the conservation purposes of the ESA to disqualify an area as ''habitat'' simply because it requires some reasonable alteration or restoration—whether through natural processes or some reasonable degree of human intervention.

It is implicit but clear, based on the statutory definition of ''critical habitat,'' that the appropriate timeframe for assessing whether physical or biological features ''are found'' in a specific area and whether specific areas ''are essential'' for a species' conservation is the time of designation (16 U.S.C. 1532(5)(A)(i)). Therefore, we do not find it necessary or appropriate to add any additional regulatory requirements regarding the timing of when certain essential features would be present in the area, or when a species may occupy or use the area. A specific unoccupied area may remain inaccessible to the listed species (*e.g.,* blocked historical spawning habitat), or may require some form of natural recovery or reasonable restoration to support the listed species over the long term (*e.g.,* upgrading old culverts), but may still be considered habitat for that species and may still be considered essential for that species' conservation if the record supports such conclusions at the time of designation. The ESA does not require the Services to know when the species is likely to benefit from a critical habitat designation to exercise our authority to designate an area as critical habitat.

The Services cannot designate as critical habitat areas that lack essential physical and biological features and then use the consultation requirements under section 7(a)(2) of the ESA to require restoration of the area. Section 7 of the ESA does not grant the Services that authority. Section 7(a)(2) of the ESA prohibits Federal actions from reducing critical habitats' capacity to conserve listed species over time; it does not impose an affirmative requirement to restore or improve any areas of critical habitat (see 81 FR 7214 at 7224, February 11, 2016 (extending to the adverse-modification analysis the conclusion in *National Wildlife Federation* v. *National Marine Fisheries Service,* 524 F.3d 917, 930 (9th Cir. 2007), that agency action can only violate section 7(a)(2) of the Act ''if that agency action causes some deterioration in the species' pre-action condition'')). In other words, the requirement for Federal agencies to ensure their actions are not likely to destroy or adversely modify critical habitat is a prohibitory standard only.

Comment 72: A commenter stated that removal of the requirement that unoccupied areas contain essential features will increase the burden on the Services to demonstrate to stakeholders that an area is habitat and is essential for the species. Several commenters note that the Services failed to identify a situation where they have designated an unoccupied area as critical habitat without an essential conservation feature or explain how an area can be essential when it lacks features the species needs.

Response: We do not agree that removal of this regulatory requirement will increase the burden on the Services to demonstrate that unoccupied areas are essential for the conservation of the listed species. With or without this requirement, the Act requires the Services to explain how the habitat is essential for the species' recovery. Mere presence of certain habitat features is not sufficient to demonstrate the features are, or the area itself is, ''essential,'' which is the required test under the ESA. Although several court rulings on this issue predate the 2019 regulation, they nonetheless speak to this statutory standard and indicate that, in designating unoccupied critical habitat, the Services must still explain how the *area* is essential for the conservation of the species. Where efforts have been made to use the presence of ''essential features'' to reach a conclusion that the area itself is essential to the conservation of the species, those efforts have failed (see *Cape Hatteras Access Pres. All.,* 344 F. Supp. 2d at 119 (''[W]ith unoccupied areas, it is not enough that the area's features be essential to conservation, the area itself must be essential.''); *Ctr. for Biological Diversity* v. *U.S. Fish & Wildlife Serv.,* 67 F.4th 1027, 1044–45 (9th Cir. 2023) (holding that ''the mere presence of pertinent biological features'' is insufficient for unoccupied areas to qualify as critical habitat); *Otay Mesa Prop., L.P.* v. *U.S. Dep't of the Interior,* 344 F. Supp. 3d 355, 376 (D.D.C. 2018) (explaining that ''the mere presence of pertinent biological features'' is insufficient for designating unoccupied critical habitat and that to do so instead requires a finding that ''the area itself is 'essential' to the conservation of the species'')).

As discussed in previous responses, we find that the 2019 regulation's requirement that unoccupied areas contain one or more essential features blurred the clear distinction between the two types of critical habitat defined in section 3 of the ESA (16 U.S.C. 1532(5)(A)) (*e.g.,* see responses to *Comment 68, Comment 70,* and *Comment 71,* above). We do not need to point to specific instances of unoccupied critical habitat that lack essential physical or biological features to rectify this issue.

Comment 73: Several commenters stated that they support the proposed removal of the ''reasonable certainty'' standard from § 424.12(b)(2) because it is potentially unlawful. Some commenters stated that this requirement is unnecessary in light of the ESA's requirement to determine critical habitat on the basis of the best scientific data available or otherwise noted that the ESA does not require a finding of ''reasonable certainty.''

Response: We appreciate the commenters' support for our proposed changes.

Comment 74: Multiple commenters opposed the proposed removal of the ''reasonable certainty'' requirement from 50 CFR 424.12(b)(2) because, in their view, removing that requirement is contrary to the ''more demanding'' standard Congress established for designating unoccupied critical habitat, and the Services should be required to make a strong case for making a determination that the areas are ''essential for conservation.'' These commenters asserted that, under the proposed regulation, the Services could base their designation on science that is not sufficiently certain. Other commenters stated that if the best available data do not contain the requisite amount of certainty, those data cannot be relied upon in making regulatory decisions. Several commenters stated that basing designation of unoccupied areas on the ''best scientific data available'' is not an adequate standard, as the ''best data'' could be poor and speculative. One commenter asserted that the proposed removal of the ''reasonable certainty'' standard indicates that the Services could rely on ''quite inconclusive'' information when designating critical habitat.

Response: Removal of the ''reasonable certainty'' standard from the regulations does not allow the Services to begin to, nor does it indicate we will, designate areas of unoccupied habitat based on unreliable or speculative data. The best-available-data standard is also not an inadequate standard; it is the statutory standard upon which we are required to base all critical habitat designations (16 U.S.C. 1533(b)(2)). As we discussed in the proposed rule, courts have held that

the ESA's ''best scientific data available'' standard does not require that the information relied upon by the Services be perfect or free from uncertainty. (See, *e.g., Oceana, Inc.* v. *Ross,* 321 F. Supp. 3d 128, 142 (D.D.C. 2018) (''[T]he plain language of the provision requires NMFS only to use the best data *available,* not the best data *possible.*'') (emphases in original); *Alaska Oil & Gas Ass'n* v. *Jewell,* 815 F.3d 544, 555 (9th Cir. 2016) (noting that the Act's best-data-available requirement does not require perfection in the data but only precludes basing decisions on speculation or surmise) (citing cases). In applying this standard, the Services cannot, and do not, simply rely on whatever data are available at the time of designation without independent evaluation; the Services must carefully review and interpret those data along with any associated assumptions and uncertainties, and then draw supportable, reasonable conclusions. The scientific information and basis for a proposed designation are also subjected to both peer and public review, which affords additional vetting and opportunity for input before a designation is finalized.

The statutory definition of ''critical habitat'' provides separate, distinct standards for defining the two types (occupied and unoccupied) of critical habitat (16 U.S.C. 1532(5)(A)). The ESA does not establish or imply there must be a greater degree of certainty in the underlying data supporting the designation of unoccupied areas relative to occupied areas. In fact, section 4(b)(2) of the ESA makes no distinction on this matter, and simply states that critical habitat must be designated ''on the basis of the best scientific data available'' (16 U.S.C. 1533(b)(2)).

Comment 75: Several commenters opposed the proposed removal from 50 CFR 424.12(b)(2) of the requirement to determine that unoccupied areas will have a reasonable certainty to contribute to the conservation of the species. One commenter stated that this provision informs the determination of whether an area is essential for the species' conservation, and that this requirement helps ensure that unoccupied areas deemed ''essential'' will benefit the species. Furthermore, the commenter stated that the regulation should be revised to provide relevant factors for determining when an unoccupied area is considered essential, and that the Services should be required to make a finding that the species will occupy the area. The commenter stated that if the species is unlikely to occupy the area, then it cannot contribute to the species' conservation.

Response: To designate an unoccupied area as critical habitat, the Services must make a determination that the specific area is ''essential for conservation.'' Whether and how an area is demonstrated to meet this statutory test will depend on the best available data for the listed species and what those data indicate in terms of the habitat and conservation needs of the species. It is possible that, in some cases, the Services will have data to show or project when the listed species may move into or reoccupy an unoccupied area of critical habitat; however, such data are not required to find that the area is ''essential'' for the conservation of that species. Rather, the Services can consider a variety of relevant factors (*e.g.,* whether the area was part of the historical range, current condition of the unoccupied habitat, planned restoration activities) when determining whether the area is essential for the species' conservation and assessing the impacts (positive and negative) of designation under section 4(b)(2) of the ESA.

Regardless of the relevant available data that are used to inform a critical habitat designation, the ESA does not require the Services to conduct a forward-looking analysis to forecast or predict when a species may occur in an area that it did not occupy at the time of listing. The ESA also does not require the Services to know when the species is likely to benefit from a critical habitat designation in order to exercise our authority to designate an area as critical habitat. As we discussed in response to *Comment 71,* the statutory definition of ''critical habitat'' indicates that the appropriate timeframe for assessing whether a specific area is ''essential'' for a species' conservation is the time of designation (16 U.S.C. 1532(5)(A)(i)). Therefore, for an unoccupied area to be considered ''essential,'' we need not determine or project when the listed species may occur in the area or benefit from the critical habitat designation. A specific unoccupied area may contain excellent habitat for a listed species but remain inaccessible to the listed species (*e.g.,* blocked historical spawning habitat) or may require some form of natural recovery or reasonable restoration to support the listed species over the long term (*e.g.,* upgrading old culverts); but in both cases, the areas may still be considered habitat for that species and may still be considered essential for that species' conservation if the evidence supports such conclusions at the time of designation.

Comment 76: A commenter stated they support the removal of the phrase ''there is a reasonable certainty . . . that the area will contribute to the conservation of the species'' from 50 CFR 424.12(b)(2) because this is an inappropriately low standard. The commenter stated that merely contributing to conservation is not equivalent or indicative of being essential or indispensable to conservation.

Response: We appreciate this commenter's point, and we agree that ''contributing to conservation'' is not an equivalent standard to the statutory standard of whether an area is ''essential'' or necessary for a species' conservation.

Comment 77: Some commenters asserted that the proposal to remove the ''reasonable certainty'' requirement from 50 CFR 424.12(b)(2) lacked a sufficient explanation. A commenter stated that the justification that this requirement could potentially conflict with the best available data requirement was not reasonable. The commenter stated that because the best-available-data standard has not previously been interpreted to require a specific level of certainty, there is no indication that any potential conflict exists. Several commenters stated they did not agree with the Services' statements in the proposed rule that imposing a ''reasonable certainty'' standard could result in some of the best available data being excluded from consideration.

Response: We respectfully disagree with these comments and continue to find that the ''reasonable certainty'' requirement in the 2019 regulation is not mandated by the language or structure of the Act, and in the view of the Services, its removal would better fulfill the Secretaries' obligation to further the conservation purposes of the Act. The best-available-data standard of the ESA already inherently contains an obligation for the Services not to base their decisions on information that is merely potential or speculative. The ''reasonable certainty'' standard appeared to set a more stringent standard relative to the statutory standard and thus could potentially result in the Services excluding data from consideration because they were deemed not to meet some ambiguously heightened level of certainty. As we also discussed in response to *Comment* 74, the ESA does not require that the supporting data be free from uncertainty (see, *e.g., Alaska Oil & Gas Ass'n* v. *Jewell,* 815 F.3d 544, 555 (9th Cir. 2016) (noting that the Act's best data available requirement does not require perfection in the data but only precludes basing decisions on speculation or surmise) (citations omitted)). The ''reasonable certainty'' standard could also

potentially lead to increased legal challenges to the Services' designations asserting either that we ignored some of the relevant available data, or that the underlying data were not sufficiently free from uncertainty. We find that the rationale and explanation for this revision is clear and reasonable, and we are finalizing the revision as proposed.

Comment 78: Several commenters noted they support the addition of the last sentence of 50 CFR 424.12(b)(2) indicating that determinations regarding whether an area is essential for a species' conservation will be based on the best scientific data available. Several commenters, however, objected to the inclusion of this phrase, stating that, while accurate, it is redundant with regulatory text at 50 CFR 424.12(a) and is also incomplete or misleading because it leaves out the requirement to consider economic, national security, and other relevant impacts.

Response: We appreciate the comments in support of this revision, and we do agree with other comments that the added sentence in 50 CFR 424.12(b)(2) is redundant with existing text in the earlier section of the regulations (50 CFR 424.12(a)). However, we have elected to repeat this statutory requirement in 50 CFR 424.12(b)(2) because it is helpful to reiterate and emphasize this important standard, particularly given the sometimes contested nature of unoccupied critical habitat designations. Also, comments we received on the proposed rule expressing concerns that the Services intend to have unfettered discretion in designating these areas reaffirm that it is helpful to reiterate in the context of unoccupied critical habitat that decisions must be made on the basis of the best scientific data available.

We do not find the text of 50 CFR 424.12(b)(2) to be incomplete or misleading because this section of the regulations is focused on the identification of areas that meet the definition of ''critical habitat'' under the ESA. Other sections of the regulations, 50 CFR 424.19 in particular, discuss other requirements of the designation and rulemaking process, and these regulations addressing critical habitat continue to apply.

Other General Comments

Comment 79: Several commenters stated that the Services did not adequately explain the proposed changes and, for that reason, the proposed regulation is arbitrary and capricious. Some commenters claimed that the Services' reliance primarily on E.O. 13990, litigation, and points that were adequately addressed in the 2019 rulemaking for its rationale for the proposed changes is insufficient.

Response: As discussed above in response to comments on specific proposed revisions, in our June 22, 2023, proposed rule (88 FR 40764), the Services thoroughly explained the proposed revisions based on our review of the 2019 regulations in light of the Act, its conservation purposes, and congressional intent. Following our review of the 2019 regulations, and as discussed more thoroughly in the responses above to comments on specific provisions, the Services have concluded that certain provisions of the 2019 regulations were not the best interpretation of the statutory standards or the best way to further the conservation purposes of the Act. Our preamble to the 2023 proposed rule identified where we were changing our positions from the prior rulemaking, and we have expanded our reasoning for those changes here in response to comments received. The 2019 rule was prompted by E.O. 13777 (82 FR 12285, March 1, 2017), which has been rescinded, as well as a settlement agreement related to litigation over the 2016 regulatory changes. We also note that, prior to 2016 there had been no comprehensive revisions to 50 CFR part 424 since 1984.

Comment 80: One commenter questioned whether the Services have adequately disclosed what they were not proposing to change in the 2019 regulations and requested the Services provide a publicly available written analysis of the sections of the regulations that would not be changed.

Response: Our June 22, 2023, proposed rule (88 FR 40764) thoroughly explained the revisions and changes that we proposed to the 2019 regulations. There is no requirement for agencies to identify portions of a rule that they do not propose to change and justify why certain provisions are being retained. We prepared a supporting document that displayed the specific, proposed line edits to the existing text in 50 CFR part 424 and made that document publicly available as part of the rulemaking docket during the public comment period. The Services have generally made revisions to all of the sections of the regulations that were revised in 2019: listing, delisting, and criteria for designating critical habitat. Those few provisions of the 2019 regulations that are not revised with this final rule remain in place. We refer commenters to the explanations provided in that rulemaking (83 FR 35193, July 25, 2018; 84 FR 45020, August 27, 2019) for the not-prudent determinations codified at 50 CFR 424.12(a)(1)(i), (iii), and (iv) (see also our responses to *Comment 48* and *Comment 49* in this document), for the changes to the definition of ''physical or biological features'' at § 424.02, and for the editorial changes to § 424.11(c).

Comment 81: A commenter requested the Services review all of the listing decisions and critical habitat determinations made under the 2019 rule. The commenter noted the original Federal court decision to vacate the entire rule indicates there are substantial issues with the rule. Consequently, some or all of the species affected by the 2019 rule may not have received the full conservation benefits of the Act when listing determinations and critical habitat designations were finalized.

Response: The specific changes to the regulations being finalized in this rule create prospective standards only. These regulations apply to classification and critical habitat rules finalized after the effective date of this rule (see **DATES**, above) and will not apply retroactively to classification and critical habitat rules finalized prior to the effective date of this rule. The Services do not intend to reevaluate any prior final listing, delisting, or reclassification determinations or previously completed critical habitat designations on the basis of this final regulation.

As noted by the commenter, the 2019 regulations have been the subject of litigation. We described the litigation in our proposed rule (88 FR 40764–40765, June 22, 2023), and we note that the court's decision to vacate the 2019 rule was not based on the merits, and that the 2019 rule was subsequently put back into effect. Due to the litigation, where there may have been some questions regarding which version of the regulations was in effect and therefore applicable, each listing, delisting, reclassification, and critical habit designation made since the initial Federal court decision has been assessed to determine whether those listing determinations and critical habitat designations would be the same under the 50 CFR part 424 regulations as they existed before 2019, and under the regulations as revised by the 2019 rule. Those assessments concluded that, while the analysis may have differed, the outcomes would not. Therefore, we conclude that it is not necessary to reevaluate any prior final listing, delisting, or reclassification determinations or completed critical habitat designations.

Comment 82: Some commenters stated the Services should fully rescind the 2019 regulations, while others said

the 2019 regulations should not be revised at all.

Response: In response to E.O. 13990 and in light of recent litigation over the 2019 rule, the Services reviewed the 2019 rule, evaluated the specific regulatory revisions promulgated through that process, and, for reasons set forth above in response to comments on the specific provisions, decided to make revisions to some of the 2019 regulations rather than fully rescinding them.

Comment 83: A commenter stated the Services should substantially revise or withdraw the June 22, 2023, proposed rule (88 FR 40764) because it will impede our ability to implement this Administration's goals for the Infrastructure Investment and Jobs Act (Pub. L. 117–58, 135 Stat. 429) and the Inflation Reduction Act (Pub. L. 117–169, 136 Stat. 1818).

Response: This rule revises and clarifies the standards for listing, delisting, reclassification determinations and critical habitat designations under the ESA. It will not directly affect this Administration's goals for the Infrastructure Investment and Jobs Act or the Inflation Reduction Act. The extent to which future species listings or designations of their critical habitat are affected by or have an effect on specific projects that stem directly from the Infrastructure Investment and Jobs Act of 2021 or the Inflation Reduction Act of 2022 will be assessed on a case-by-case basis through section 7 consultation as specific projects are planned and implemented.

Comment 84: Some commenters noted the regulations governing listing and critical habitat designation have changed frequently in recent years, creating uncertainty for the regulated public.

Response: The Services acknowledge that there have been several recent revisions to the listing and critical habitat regulations and that revisions adopted in 2016 and 2019 were both challenged in subsequent litigation. However, following a review of the 2019 regulations prompted by E.O. 13990, and in response to the litigation on the 2019 rule and other ESA regulation revisions finalized in 2019, the Services determined that it is appropriate and necessary to revise these regulations so that the Services could best fulfill their duties under the Act with clear guidance. Moreover, changes to general implementing regulations related to listing and critical habitat cannot give any certainty as to a particular outcome of a listing determination or critical habitat designation due to the fact-specific nature of such rules. The process for revising regulations is governed by the APA as interpreted by relevant case law, with which the Services have complied fully. The explanation for the changes finalized today, as well as extensive responses to comments, are intended to reduce any confusion or uncertainty created by these changes.

Comment 85: A commenter stated the proposed rule is overly technical and that the final rule should contain additional information making it more understandable for the general public.

Response: We are required by E.O.s 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. We have explained the regulatory changes finalized in this rule as plainly and simply as possible. The Services received more than 160,000 comments on the proposed rule, indicating the general public was able to understand its provisions. We do not believe additional information needs to be provided in this document to make the final rule more understandable to the general public, but we did try to make some of the explanations in this final rule clearer.

Comment 86: Some commenters stated the regulation violates the ''major questions doctrine'' because the rule would give the Services the ability to make decisions based on tenuous scientific information with indefinite timeframes, unfettered ability to regulate lands through designations of unoccupied critical habitat, and discretionary delisting procedures. They stated that these actions may exceed the scope of the ESA as envisioned by Congress and may violate the major questions doctrine.

Response: The Services disagree with the commenters' characterization of the rule and their statement that these regulations violate the major questions doctrine. The doctrine is a legal principle articulated by the Supreme Court in *West Virginia* v. *EPA,* 142 S. Ct. 2587 (2022), and relied upon in *Biden* v. *Nebraska,* 143 S. Ct. 2355 (2023), the latter of which is referenced by the commenter. While clear parameters to this doctrine are difficult to discern, it generally involves an inquiry into whether Congress intended to confer on an agency the authority to address a matter of economic and political significance. (See generally *West Virginia,* 142 S. Ct. at 2608; *Biden,* 143 S. Ct. at 2372–73.) Here, Congress provided the requisite authority. We recognize that implementation of the ESA is often contested, as reflected in the numerous public comments on the proposed rule. Nonetheless, Congress entrusted the Services with the authority to implement the ESA and develop regulations that interpret the Act in furtherance of its purposes in a consistent and transparent manner. This final rule fills in some details to implement express authority provided to the Services by the Act and does not exceed the scope of this authority. Moreover, these regulations do not give the Services the ability to make decisions based on tenuous scientific information with indefinite timeframes, give the Services the unfettered ability to regulate land, or make delisting discretionary. This rule revises and clarifies requirements for NMFS and FWS in classifying species and designating critical habitat in a manner most consistent with the language and conservation purposes of the Act.

Comments on Required Determinations

Comment 87: A commenter stated that the Services should pause this rulemaking to evaluate impacts under E.O. 12866, as our proposal was identified as a significant rule. They stated the review process for the proposed rule must comply with the requirements for regulatory planning, coordination, and review specified in E.O. 12866 and related directives, including an economic analysis of the proposed rule.

Response: Executive Order 12866, as amended by E.O. 14094, provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) will review all significant rules. OMB designated the June 22, 2023, proposed rule (88 FR 40764) as ''significant'' pursuant to E.O. 12866 but did not characterize the rulemaking as significant under section 3(f)(1) of E.O. 12866. Therefore, we are not required to conduct an economic analysis of the rule.

Executive Order 14094 amends E.O. 12866, reaffirms the principles of E.O. 12866 and E.O. 13563, and states that regulatory analysis should facilitate agency efforts to develop regulations that serve the public interest, advance statutory objectives, and be consistent with E.O. 12866, E.O. 13563, and the Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review). E.O. 14094 states that regulatory analysis, as practicable and appropriate, shall recognize distributive impacts and equity to the extent permitted by law. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have

developed this final rule in a manner consistent with these requirements.

The revisions we are finalizing to the listing, delisting, and reclassification regulations as described in this rule are intended to align more closely with the Act and to provide transparency and clarity—not only to the public and stakeholders, but also to the Services' staff in the implementation of the Act. Similarly, the revisions to the provisions related to the Secretaries' duty to designate critical habitat are intended to align the regulations with the Act. These changes provide transparency and clarity, and there are no identifiable, quantifiable effects from the final rule. Further, we do not anticipate any material effects such that the rule would have an annual effect that would reach or exceed $200 million or would 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, territorial, or Tribal governments or communities.

Comment 88: Some commenters stated that we need to conduct an evaluation of economic impacts under E.O. 12866 and the Regulatory Flexibility Act. Others stated that because OMB deemed the rule significant under E.O. 12866, the Services' determination that the rule would not have a significant effect on small entities was in error. Several commenters stated that the rule would directly and significantly affect small entities; as such, the Services should conduct a regulatory flexibility analysis.

Response: This final rule does not violate E.O. 12866 or the Regulatory Flexibility Act. We do not anticipate any material effects such that the rule would have an annual effect that would reach or exceed $200 million or would 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, territorial, or Tribal governments or communities.

Under the Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996; 5 U.S.C. 601 *et seq.*), whenever a Federal agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare, and make available for public comment, a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency, or that person's designee, certifies that the rule will not have a significant economic impact on a substantial number of small entities. We have certified that these regulations will not have a significant economic impact on a substantial number of small entities because this rule revises and clarifies requirements for NMFS and FWS in classifying species and designating critical habitat under the Act and does not directly affect small entities (see 88 FR 40764 at 40772, June 22, 2023). Further, regarding the comment that because OMB deemed the rule significant under E.O. 12866, the rule is also significant under RFA, we disagree. The criteria for identifying a significant regulatory action under E.O. 12866 are not the same as the criteria for identifying a rule that will have a significant economic impact on a substantial number of small entities pursuant to the RFA. See Required Determinations, below, for further discussion of E.O. 12866 and the RFA.

Comment 89: Some commenters stated the Services should prepare an environmental impact statement or an environmental assessment under NEPA and stated that a categorical exclusion is not appropriate for this rule. One commenter requested that, if an environmental assessment is prepared, it be made available for public comment and that any categorical exclusion be made available for public inspection.

Response: We have analyzed this regulation in accordance with the criteria of NEPA, the Department of the Interior regulations on implementation of NEPA (43 CFR 46.10–46.450), the Department of the Interior Manual (516 DM 8), the National Oceanic and Atmospheric Administration (NOAA) Administrative Order 216–6A, and the companion manual, ''Policy and Procedures for Compliance with the National Environmental Policy Act and Related Authorities,'' which became effective January 13, 2017. We have concluded a categorical exclusion is appropriate for this rulemaking. For more-specific information regarding our conclusions regarding categorical exclusion under NEPA, see Required Determinations, below. The categorical exclusion memoranda developed by the Services are available online (see **ADDRESSES**, above).

Comment 90: One commenter stated the Services should have provided a statement of energy effects under E.O. 13211 and, because of the adverse energy effects of the rule, should prepare reasonable alternatives to the action.

Response: Because this final rule is promulgating interpretive rules that govern the Services' implementation of the ESA, this action is not expected to affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action, and no statement of energy effects is required. Furthermore, to the extent that there may be any energy effects from future critical habitat determinations, the Services will be required to consider those effects pursuant to E.O. 13211 in the context of those species-specific rulemakings.

Comment 91: A few commenters stated that the proposed regulatory change violates E.O. 13777.

Response: Executive Order 13777 was revoked by President Biden on January 20, 2021, and is longer in effect. Moreover, by its terms, E.O. 13777 did not create any enforceable rights or benefits against the United States.

Comment 92: A commenter stated the proposed rule would affect States and, therefore, disagrees with the Services' conclusion that a federalism summary impact statement under E.O. 13132 is not required.

Response: As stated below under Required Determinations in *Federalism (E.O. 13132),* the Services have determined, in accordance with E.O. 13132, that this final rule will not have significant federalism effects and have determined that a federalism summary impact statement is not required. This final rule pertains only to factors for listing, delisting, or reclassifying species and designation of critical habitat under the Act and does not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Furthermore, to the extent that there may be any federalism effects from future critical habitat determinations, the Services will be required to consider those effects pursuant to E.O. 13132 in the context of those species-specific rulemakings.

Comment 93: A commenter stated the rule could result in takings and the Services should reconsider our findings under E.O. 12630.

Response: The Services have concluded, in accordance with E.O. 12630, that this final rule will not have significant takings implications. As discussed in the June 22, 2023, proposed rule and below under Required Determinations, this rule does not pertain to taking of private property interests, nor does it directly affect private property. A takings implication assessment is not required because this rule will not effectively compel a property owner to suffer a physical invasion of property and will not deny

all economically beneficial or productive use of the land or aquatic resources. This rule substantially advances a legitimate government interest (conservation and recovery of endangered species and threatened species) and does not present a barrier to all reasonable and expected beneficial use of private property. To the extent that there may be any takings implications as a result of future critical habitat determinations, the Services will be required to consider those implications pursuant to E.O. 12630 in the context of those species-specific rulemakings.

Comment 94: A commenter stated the Services will violate section 7(a)(2) of the ESA if they do not consult on this final rule. They stated that if the Services finalize the rule without completing consultation under section 7(a)(2), they will violate section 7(d) of the ESA, which prohibits Federal agencies from making any irreversible or irretrievable commitment of resources with respect to the agency action once consultation has been initiated.

Response: In finalizing this rule, the Services are acting in their statutory roles as administrators of the ESA and are engaged in a legal exercise of interpreting the standards of the ESA. The Services' promulgation of interpretive rules that govern the implementation of the ESA is not an action that is in itself subject to the ESA's provisions, including section 7(a)(2). The Services have a historical practice of issuing their general implementing regulations under the ESA without undertaking section 7 consultation. Given the plain language, structure, and purposes of the ESA, we find that Congress never intended to place a consultation obligation on the Services' promulgation of implementing regulations under the ESA. In contrast to actions in which we have acted principally as an ''action agency'' in implementing the ESA to propose or take a specific action (*e.g.,* issuance of section 10 permits and actions under statutory authorities other than the ESA), here, the Services are carrying out an action that is at the very core of their unique statutory role as administrators—promulgating general implementing regulations or revisions to those regulations that interpret the terms and standards of the Act.

Comment 95: A commenter stated that the Services have not adequately consulted with Alaska Native Corporations and that they have an obligation under E.O. 13175 to consult with Alaska Native Corporations on the same basis as Tribes. Consistent with this obligation, the Services should commit to consulting with Alaska Native Corporations on the designation of critical habitat in Alaska.

Response: In accordance with E.O. 13175 ''Consultation and Coordination with Indian Tribal Governments,'' the Department of the Interior's manual at 512 DM 2, the Department of Commerce (DOC) ''Tribal Consultation and Coordination Policy'' (May 21, 2013), DOC Departmental Administrative Order (DAO) 218–8, and NOAA Administrative Order (NAO) 218–8 (April 2012), we considered possible effects of this rule on federally recognized Indian Tribes. This rule is general in nature and does not directly affect any specific Tribal lands, treaty rights, or Tribal trust resources. Therefore, we concluded that this rule does not have ''Tribal implications'' under section 1(a) of E.O. 13175. However, the Services did conduct several webinars on the proposed rule specifically targeted to Tribes and Alaska Natives.

A number of recent memoranda and Executive orders describe the commitment of the U.S. Government to strengthening the relationship between the Federal Government and Tribal Nations and to advance equity for Indigenous people, including Native Americans, Alaska Natives, Native Hawaiians, and Indigenous peoples of the U.S. Territories. These include the Memorandum on Tribal Consultation and Strengthening Nation-to-Nation Relationships (86 FR 7491, January 29, 2021); Executive Order 13985: Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (86 FR 7009, January 25, 2021); Executive Order 14031: Advancing Equity, Justice, and Opportunity for Asian Americans, Native Hawaiians, and Pacific Islanders (86 FR 29675, June 3, 2021); and the Memorandum on Indigenous Traditional Ecological Knowledge and Federal Decision Making (November 15, 2021). The commitments described in these recent Executive orders and memoranda include ensuring that Federal agencies conduct regular, meaningful, and robust consultation with Tribal officials in the development of Federal research, policies, and decisions, especially decisions that may affect Tribal Nations and the people they represent. Our obligation to have a government-to-government relationship with federally recognized Tribes is paramount and, in addition to Executive orders and policies on the government-to-government relationship, is covered by Secretaries' Orders (S.O.) 3206 and 3225. While S.O. 3225 discusses ''Alaska Natives'' and ''other Native organizations,'' its purpose is to protect subsistence rights and ways of life, and states that Departments of Commerce and the Interior will seek to enter into cooperative agreements for the conservation of specific species, such as marine mammals and migratory birds, and the co-management of subsistence uses with these organizations.

In the Consolidated Appropriations Act of 2004 (Pub. L. 108–199, Div. H, sec. 161), Congress required that the Director of the Office of Management and Budget (and, subsequently, all Federal agencies) consult with Alaska Native Corporations on the same basis as Indian Tribes under Executive Order 13175. Consistent with this obligation, the Services will consult on Federal decisions that have a substantial, direct effect on an Alaska Native Corporation. This obligation to consult does not extend beyond the E.O. 13175 context.

Required Determinations

Regulatory Planning and Review—Executive Orders 12866, 13563, and 14094

Executive Order 12866, as amended by Executive Order 14094, provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA determined that this final rule is significant as defined by Executive Order 12866.

Executive Order 14094 amends E.O. 12866 and reaffirms the principles of E.O. 12866 and E.O 13563 and states that regulatory analysis should facilitate agency efforts to develop regulations that serve the public interest, advance statutory objectives, and be consistent with E.O. 12866, E.O. 13563, and the Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review). Regulatory analysis, as practicable and appropriate, shall recognize distributive impacts and equity to the extent permitted by law. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements. This rule is consistent with E.O. 13563 and in particular with the requirement of retrospective analysis of existing rules designed ''to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives.''

This rule revises the Services' implementing regulations at 50 CFR 424.11 and 424.12. Specifically, the

Services are finalizing changes to implementing regulations at: (1) § 424.11(b), the factors for listing, delisting, or reclassifying species; (2) § 424.11(d), the foreseeable future framework; (3) § 424.11(e), the standards for delisting; (4) § 424.12(a), the criteria for not-prudent determinations for critical habitat; and (5) § 424.12(b)(2), the criteria for designation of unoccupied critical habitat. The preamble to this rule and responses to public comments explain in detail why we anticipate that the regulatory changes we are finalizing will improve the implementation of the Act.

When we made changes to these same sections in 2019, we compiled historical data on the occurrence of specific metrics of listing and critical habitat determinations by the Services in an effort to describe for OMB and the public the potential scale of any effects of those regulations (on *https://www.regulations.gov,* see Supporting Document No. FWS–HQ–ES–2018–0006–0002 of Docket No. FWS–HQ–ES–2018–0006). We presented various metrics related to the regulation revisions, as well as historical data supporting the metrics.

For the 2019 regulations, we concluded—with respect to the provisions related to listing, reclassification, and delisting of species—that, because those revisions served to clarify rather than alter the standards for classifying species, the 2019 regulation revisions would not change the average number of species classification (*i.e.,* listing, reclassification, delisting) outcomes per year. With respect to the critical habitat provisions, we concluded that, because the outcomes of critical habitat determinations are highly fact-based, it was not possible to forecast reliably whether more or fewer not-prudent determinations or designations of unoccupied critical habitat would be made each year if the 2019 regulation revisions were finalized.

The revisions we are now finalizing to the listing, delisting, and reclassification provisions as described above are intended to align more closely with the Act and to provide transparency and clarity—not only to the public and stakeholders, but also to the Services' staff—in the implementation of the Act. As a result, we do not anticipate any change in the rate or frequency or particular classification outcomes due to the revised regulation. Similarly, the revisions to the provisions related to the Secretaries' duty to designate critical habitat are intended to align the regulations with the Act, and—because the outcomes of critical habitat analyses are so highly fact-specific and it is not possible to forecast how many related circumstances will arise—any future benefit or cost stemming from these revisions is currently unknowable.

These changes provide transparency and clarity, and there are no identifiable, quantifiable effects from this rule. Further, we do not anticipate any material effects such that the rule would have an annual effect that would reach or exceed $200 million or would 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, territorial, or Tribal governments or communities.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996; 5 U.S.C. 601 *et seq.*), whenever a Federal agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare, and make available for public comment, a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency, or that person's designee, certifies that the rule will not have a significant economic impact on a substantial number of small entities. SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities. We certified at the proposed rule stage that the proposed rule would not have a significant economic impact on a substantial number of small entities (88 FR 40764 at 40772, June 22, 2023). Nothing in this final rule changes the basis for that conclusion, and we received no information that changes the factual basis of this certification.

This rule revises and clarifies requirements for NMFS and FWS in classifying species and designating critical habitat under the Act and does not directly affect small entities. NMFS and FWS are the only entities that will be directly affected by this rule because we are the only entities that list species and designate critical habitat under the ESA. External entities, including any small businesses, small organizations, or small governments, are not directly regulated by this rule and thus will not experience any direct economic impacts from this rule.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*):

(a) On the basis of information presented under *Regulatory Flexibility Act* above, this rule will not ''significantly or uniquely'' affect small governments. We have determined and certify pursuant to the Unfunded Mandates Reform Act that this final rule will not impose a cost of $100 million or more in any given year on local or State governments or private entities. A small government agency plan is not required. As explained above, small governments will not be affected because the final rule will not place additional requirements on any city, county, or other local municipalities.

(b) This rule will not produce a Federal mandate on State, local, or Tribal governments or the private sector of $100 million or greater in any year; that is, this final rule is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act. This final rule will impose no obligations on State, local, or Tribal governments.

Takings (E.O. 12630)

In accordance with Executive Order 12630, this rule will not have significant takings implications. This rule does not pertain to ''taking'' of private property interests, nor will it directly affect private property. A takings implication assessment is not required because this final rule (1) will not effectively compel a property owner to suffer a physical invasion of property and (2) will not deny all economically beneficial or productive use of the land or aquatic resources. This rule substantially advances a legitimate government interest (conservation and recovery of endangered species and threatened species) and will not present a barrier to all reasonable and expected beneficial use of private property.

Federalism (E.O. 13132)

In accordance with Executive Order 13132, we have considered whether this rule will have significant federalism effects and have determined that a federalism summary impact statement is not required. This rule pertains only to factors for listing, delisting, or reclassifying species and designation of critical habitat under the ESA and will not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Civil Justice Reform (E.O. 12988)

This rule does not unduly burden the judicial system and meets the applicable standards provided in sections 3(a) and 3(b)(2) of Executive Order 12988. This rule clarifies factors for listing, delisting, or reclassifying species and designation of critical habitat under the ESA.

Government-to-Government Relationship With Tribes

In accordance with Executive Order 13175 ''Consultation and Coordination with Indian Tribal Governments,'' the Department of the Interior's (DOI) manual at 512 DM 2, the Department of Commerce's (DOC) ''Tribal Consultation and Coordination Policy'' (May 21, 2013), DOC Departmental Administrative Order (DAO) 218–8, and NOAA Administrative Order (NAO) 218–8 (April 2012), we considered possible effects of this rule on federally recognized Indian Tribes and Alaska Native Corporations. We held three informational webinars for federally recognized Tribes in January 2023, before the June 22, 2023, proposed rule published, to provide a general overview of, and information on how to provide input on, a series of rulemakings related to implementation of the Act that the Services were developing, including the June 22, 2023, proposed rule to revise our regulations at 50 CFR part 424 (88 FR 40764). In July 2023, we also held six informational webinars after the proposed rule published, to provide additional information to interested parties, including Tribes, regarding the proposed regulations. More than 500 attendees, including representatives from federally recognized Tribes and Alaska Native Corporations, participated in these sessions, and we addressed questions from the participants as part of the sessions. We received written comments from Tribal organizations; however, we did not receive any requests for coordination or government-to-government consultation from any federally recognized Tribes.

This rule is general in nature and does not directly affect any specific Tribal lands, treaty rights, or Tribal trust resources. Therefore, we conclude that this rule does not have Tribal implications under section 1(a) of E.O. 13175. Thus, formal government-to-government consultation is not required by E.O. 13175 and related policies of the DOI and DOC. This rule revises regulations for protecting endangered and threatened species pursuant to the Act. These regulations will 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.

Although this rule does not have ''tribal implications'' under section 1(a) of E.O. 13175, we will continue to collaborate with Tribes and Alaska Native Corporations on issues related to federally listed species and their habitats and will work with them as we implement the provisions of the Act. See Joint Secretaries' Order 3206 (''American Indian Tribal Rights, Federal 2012; Tribal Trust Responsibilities, and the Endangered Species Act'', June 5, 1997) and Secretaries' Order 3225 (''Endangered Species Act and Subsistence Uses in Alaska (Supplement to Secretarial Order 3206),'' January 19, 2001).

Paperwork Reduction Act

This final rule does not contain any new collection of information that requires approval by the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act

We have analyzed this final regulation in accordance with the criteria of NEPA, the Department of the Interior regulations on implementation of NEPA (43 CFR 46.10–46.450), the Department of the Interior Manual (516 DM 8), the NOAA Administrative Order 216–6A, and the companion manual, ''Policy and Procedures for Compliance with the National Environmental Policy Act and Related Authorities,'' which became effective January 13, 2017.

On June 3, 2023, NEPA was amended by the Fiscal Responsibility Act (Pub. L. 118–5). These amendments codified a procedure for determining the appropriate level of NEPA review. Under these statutory standards, which generally reflect the same standards previously applicable by regulation, an environmental impact statement is only required for an action that has a reasonably foreseeable significant effect on the quality of the human environment. An environmental assessment is not required for actions that do not have a reasonably foreseeable significant effect on the quality of the human environment, or have effects of unknown significance, if the agency finds, *inter alia,* that the action is excluded pursuant to one of the agency's categorical exclusions.

We have determined that a detailed statement under NEPA is not required because the rule is covered by a categorical exclusion. We have also determined that the rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 or listed in NOAA's NEPA companion manual (CM) that would require further analysis under NEPA.

Under DOI's NEPA procedures, DOI has found that the following categories of actions would not individually or cumulatively have a significant effect on the human environment and are, therefore, categorically excluded from the requirement for completion of an environmental assessment or environmental impact statement: Policies, directives, regulations, and guidelines: that are of an administrative, financial, legal, technical, or procedural nature (43 CFR 46.210(i)). NOAA's NEPA procedures include a similar categorical exclusion for ''preparation of policy directives, rules, regulations, and guidelines of an administrative, financial, legal, technical, or procedural nature'' (categorical exclusion G7, at CM appendix E). This rule does not involve any of the extraordinary circumstances provided in NOAA's NEPA procedures, and therefore does not require further analysis to determine whether the action may have significant effects (CM at 4.A).

As a result, we find that the categorical exclusion found at 43 CFR 46.210(i) and in the NOAA CM applies to this regulation, and neither Service has identified any extraordinary circumstances that would preclude this categorical exclusion.

Endangered Species Act

In developing this rule, the Services are acting in their unique statutory role as administrators of the Act and are engaged in a legal exercise of interpreting the standards of the Act. The Services' promulgation of interpretive rules that govern their implementation of the Act is not an action that is in itself subject to the Act's provisions, including section 7(a)(2). The Services have a historical practice of issuing their general implementing regulations under the ESA without undertaking section 7 consultation. Given the plain language, structure, and purposes of the ESA, we find that Congress never intended to place a consultation obligation on the Services' promulgation of implementing regulations under the Act. In contrast to actions in which we have acted principally as an ''action agency'' in implementing the Act to propose or take a specific action (*e.g.,* issuance of section 10 permits and actions under statutory authorities other than the

ESA), here the Services are carrying out an action that is at the very core of their unique statutory role as administrators—promulgating general implementing regulations or revisions to those regulations that interpret the terms and standards of the Act.

Energy Supply, Distribution or Use (E.O. 13211)

Executive Order 13211 requires agencies to prepare statements of energy effects when undertaking certain actions. These revised regulations are not expected to affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action, and no statement of energy effects is required.

Authority

We issue this final rule under the authority of the Endangered Species Act, as amended (16 U.S.C. 1531 *et seq.*).

List of Subjects in 50 CFR Part 424

Administrative practice and procedure, Endangered and threatened species.

Regulation Promulgation

For the reasons set out in the preamble, we hereby amend part 424, subchapter A of chapter IV, title 50 of the Code of Federal Regulations, as set forth below:

PART 424—LISTING ENDANGERED AND THREATENED SPECIES AND DESIGNATING CRITICAL HABITAT

■ 1. The authority citation for part 424 continues to read as follows:

Authority: 16 U.S.C. 1531 et seq.

■ 2. Amend § 424.11 by:

■ a. In paragraph (a), removing the text ''§ 424.02(k)'' and adding in its place the text ''§ 424.02''; and

■ b. Revising paragraphs (b), (d), and (e) to read as follows:

§ 424.11 Factors for listing, delisting, or reclassifying species.

* * * * *

(b) The Secretary shall make any determination required by paragraphs (c), (d), and (e) of this section solely on the basis of the best available scientific and commercial information regarding a species' status without reference to possible economic or other impacts of such determination.

* * * * *

(d) In determining whether a species is a threatened species, the Services must analyze whether the species is likely to become an endangered species within the foreseeable future. The foreseeable future extends as far into the future as the Services can make reasonably reliable predictions about the threats to the species and the species' responses to those threats. The Services will describe the foreseeable future on a case-by-case basis, using the best available data and taking into account considerations such as the species' life-history characteristics, threat-projection timeframes, and environmental variability. The Services need not identify the foreseeable future in terms of a specific period of time.

(e) Species will be delisted if the Secretary determines, based on consideration of the factors and standards set forth in paragraph (c) of this section, that the best scientific and commercial data available substantiate that:

(1) The species is extinct;

(2) The species has recovered to the point at which it no longer meets the definition of an endangered species or a threatened species;

(3) New information that has become available since the original listing decision shows the listed entity does not meet the definition of an endangered species or a threatened species; or

(4) New information that has become available since the original listing decision shows the listed entity does not meet the definition of a species.

* * * * *

■ 3. Amend § 424.12 by:

■ a. Revising the introductory text of paragraph (a)(1) and paragraphs (a)(1)(ii) through (iv);

■ b. Removing paragraph (a)(1)(v); and

■ c. Revising paragraph (b)(2).

The revisions read as follows:

§ 424.12 Criteria for designating critical habitat.

(a) * * *

(1) Designation of critical habitat may not be prudent in circumstances such as, but not limited to, the following:

* * * * *

(ii) The present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species;

(iii) Areas within the jurisdiction of the United States provide no more than negligible conservation value, if any, for a species occurring primarily outside the jurisdiction of the United States; or

(iv) No areas meet the definition of critical habitat.

* * * * *

(b) * * *

(2) After identifying areas occupied by the species at the time of listing, the Secretary will identify, at a scale determined by the Secretary to be appropriate, specific areas outside the geographical area occupied by the species at the time of listing that the Secretary determines are essential for the conservation of the species. Such a determination must be based on the best scientific data available.

* * * * *

Shannon A. Estenoz,

Assistant Secretary for Fish and Wildlife and Parks, Department of the Interior.

Richard W. Spinrad,

Under Secretary of Commerce for Oceans and Atmosphere, NOAA Administrator, National Oceanic and Atmospheric Administration.

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