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Title 3—

The President

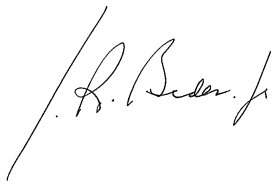
Memorandum of December 20, 2024

Delegation of Authority Under Section 506(a)(3) of the Foreign Assistance Act of 1961

Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 621 of the Foreign Assistance Act of 1961 (FAA), I hereby delegate to the Secretary of State the authority under section 506(a)(3) of the FAA to direct the drawdown of up to $571.3 million in defense articles and services of the Department of Defense, and military education and training, to provide assistance to Taiwan.

You are authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, December 20, 2024

[FR Doc. 2025–00260
Filed 1–6–25; 8:45 am]
Billing code 4710–10–P

Presidential Documents

Proclamation 10878 of December 31, 2024

National Mentoring Month, 2025

By the President of the United States of America

A Proclamation

Leading by the power of their example, mentors represent the very best of America's spirit of community and care for one another. During National Mentoring Month, we honor all the Americans who give their time and their hearts to mentor our Nation's young people.

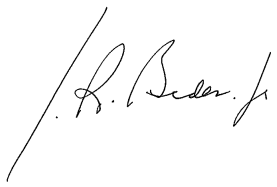
My Administration has been committed to giving youths the resources they need to thrive, including by ensuring students feel supported and have opportunities to connect to meaningful mentors. My American Rescue Plan secured a record $130 billion for K–12 schools, putting more teachers, counselors, social workers, and staff in our schools, who are so often our young people's first mentors. And that law gave AmeriCorps funding to support new mentors and volunteers who can serve our communities. Moreover, my Administration created the National Partnership for Student Success, which recruited more than 300,000 tutors and mentors to help young people reach their full potential, as well as student success coaches and postsecondary transition coaches. We also called on colleges and universities to use at least 15 percent of their Federal work study funds to assist their students in serving as mentors and other critical volunteer roles that support our Nation's children and youth.

At the same time, my Administration recognizes the value of mentorship in the workplace, and Registered Apprenticeships not only help provide it, they also produce some of the best workers in the world. That is why I am proud to have worked with labor unions and made historic investments in pre-apprenticeship and Registered Apprenticeship programs that provide the training and skills necessary to get a good job and launch a fulfilling career. My Administration also launched the American Climate Corps to put over 20,000 Americans to work in fast-growing green sectors like clean energy and conservation.

I have often said that we are a great Nation because we are a good people. During National Mentoring Month, we honor all the good people across our Nation, who are helping young people find direction, grow, and tap into our Nation's unlimited possibilities. As so many mentors know, being a mentor can be a transformative and enriching life experience. I encourage every American—whether you are a college student, community leader, or person hoping to make a difference—to explore opportunities to mentor or tutor by visiting americorps.gov/serve and partnershipstudentsuccess.org.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim January 2025 as National Mentoring Month. I call upon Americans across the country to observe this month with mentoring, appropriate ceremonies, activities, and programs.

IN WITNESS WHEREOF, I have hereunto set my hand this thirty-first day of December, in the year of our Lord two thousand twenty-four, and of the Independence of the United States of America the two hundred and forty-ninth.



[FR Doc. 2025–00227
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Billing code 3395–F4–P

Presidential Documents

Proclamation 10879 of December 31, 2024

National Stalking Awareness Month, 2025

By the President of the United States of America

A Proclamation

During National Stalking Awareness Month, we honor the courage and resilience of the millions of people in America who have suffered from stalking and recommit to ensuring every American feels safe and protected from this abuse. And we recommit to building a world where every person can walk through life knowing they are safe, secure, and will be treated with respect.

For the one in three women and one in six men who have endured stalking, the fear it causes can be all-consuming. No matter where it was committed or who it was committed by—at home, at work, online, or by a stranger or a neighbor—stalking can destroy a person's sense of security and safety. And it can have immense consequences on their lives: some have to leave everything behind to flee at a moment's notice or are haunted by their experience forever. It is wrong.

For too long, people refused to talk about stalking and other forms of gender-based violence, leaving survivors feeling alone, isolated, and forgotten. That changed with the passage of the landmark Violence Against Women Act more than 30 years ago—a law I was proud to write and champion as a United States Senator. It helped shine a harsh light on the scourge of gender-based violence in America and ensured that survivors were getting the support they needed. In 2022, I signed a reauthorization of the law, giving survivors of stalking more support and cracking down on perpetrators. It expanded the jurisdiction of Tribal courts to prosecute non-Native perpetrators of stalking and other gender-based violence, while ensuring survivors can bring a civil lawsuit in Federal court against someone who shared intimate images of them online without their consent.

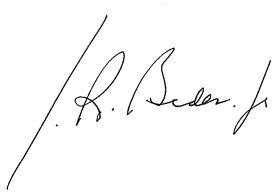
My Administration has taken action to crack down on stalking and gender-based violence in America. We released our Nation's first-ever National Plan to End Gender-Based Violence, laying out a strategy to best support survivors, work on prevention, and ensure perpetrators are held accountable. The Department of Justice's Office on Violence Against Women has continued providing grants to community organizations, prosecutors, and law enforcement to stop stalking and other gender-based crimes. And to ensure victims have a safe place to call home and rebuild their lives, the Department of Housing and Urban Development has provided tens of thousands of emergency housing vouchers. Furthermore, I established the White House Task Force to Address Online Harassment and Abuse to make sure we are stopping gender-based violence committed online.

My father used to say that one of the greatest sins a person could commit is the abuse of power—and that is fundamentally what stalking is. During National Stalking Awareness Month, we recommit to supporting survivors of stalking and reaffirm that harassment, abuse, and violence have no place in America.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim January 2025 as National Stalking Awareness Month. I call on all Americans to speak out

against stalking and to support the efforts of advocates, courts, service providers, and law enforcement to help those who are targeted and send the message to perpetrators that these crimes will not go unpunished.

IN WITNESS WHEREOF, I have hereunto set my hand this thirty-first day of December, in the year of our Lord two thousand twenty-four, and of the Independence of the United States of America the two hundred and forty-ninth.



[FR Doc. 2025–00228
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Rules and Regulations

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DEPARTMENT OF ENERGY

10 CFR Part 431

[EERE–2017–BT–STD–0009]

RIN 1904–AD79

Energy Conservation Program: Energy Conservation Standards for Walk-In Coolers and Walk-In Freezers

Correction

In rule document 2024–28474 beginning on page 104616 in the issue of Monday, December 23, 2024, make the following correction:

§ 431.306 [Corrected]

On page 104854, in Table 4 to paragraph (e)(1), in the fourth row, in the second column the text should read as follows: $9.091 \times 10^{-5} \times q_{net} + 1.81$

[FR Doc. C1–2024–28474 Filed 1–6–25; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–2367; Airspace Docket No. 24–ASW–17]

RIN 2120–AA66

Amendment of Class E Airspace; Giddings, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace at Giddings, TX. This action is the result of airspace reviews conducted due to the decommissioning of the Industry very high frequency omnidirectional range (VOR) as part of the VOR Minimum Operational Network (MON) Program. The geographic coordinates of the airport are also being updated to coincide with the FAA's aeronautical database. This action brings the airspace into compliance with FAA orders and supports instrument flight rule (IFR) operations and procedures.

DATES: Effective 0901 UTC, April 17, 2025. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: A copy of the Notice of Proposed Rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at *www.regulations.gov* using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class E airspace extending upward from 700 feet above the surface at Giddings-Lee County Airport, Giddings, TX, to support IFR operations at this airport.

History

The FAA published an NPRM for Docket No. FAA–2024–2367 in the **Federal Register** (89 FR 84304; October 22, 2024) proposing to amend the Class E airspace at Giddings, TX. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Incorporation by Reference

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11J, dated July 31, 2024, and effective September 15, 2024. FAA Order JO 7400.11J is publicly available as listed in the **ADDRESSES** section of this document. These amendments will be published in the next update to FAA Order JO 7400.11.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 modifies the Class E airspace extending upward from 700 feet above the surface to within a 6.9-mile (increased from a 6.6-mile) radius of the Giddings-Lee County Airport, Giddings, TX; and updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial

number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASW TX E5 Giddings, TX [Amended]

Giddings-Lee County Airport, TX
(Lat 30°10′09″ N, long 96°58′48″ W)

That airspace extending upward from 700 feet above the surface within a 6.9-mile radius of Giddings-Lee County Airport.

* * * * *

Issued in Fort Worth, Texas, on December 31, 2024.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2024–31643 Filed 1–6–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–2369; Airspace Docket No. 24–AGL–25]

RIN 2120–AA66

Amendment of Class E Airspace; Gaylord, MI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace at Gaylord, MI. This action is the result of an airspace review conducted due to the decommissioning of the Gaylord very high frequency omnidirectional range (VOR) as part of the VOR Minimum Operational Network (MON) Program. This action brings the airspace into compliance with FAA orders and supports instrument flight rule (IFR) procedures and operations.

DATES: Effective 0901 UTC, April 17, 2025. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: A copy of the Notice of Proposed Rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at *www.regulations.gov* using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class E airspace extending upward from 700 feet above the surface at Gaylord Regional Airport, Gaylord, MI, to support IFR operations at this airport.

History

The FAA published an NPRM for Docket No. FAA–2024–2369 in the **Federal Register** (89 FR 84313; October 22, 2024) proposing to amend the Class E airspace at Gaylord, MI. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Incorporation by Reference

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11J, dated July 31, 2024, and effective September 15, 2024. FAA Order JO 7400.11J is publicly available as listed in the **ADDRESSES** section of this document. These amendments will be published in the next update to FAA Order JO 7400.11.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 modifies the Class E airspace extending upward from 700 feet above the surface to within a 6.6-mile (reduced from a 7-mile) radius of Gaylord Regional Airport, Gaylord, MI; removes the Gaylord VORTAC and associated extensions from the airspace legal description; modifies the extension east of the airport to 2 miles each side of the 090° bearing from the airport extending from the 6.6-mile (previously 7-mile) radius of the airport to 10.5 miles east of the airport; adds an extension 9.5 miles north and 6 miles south of the 270° bearing from the Gaylord RGNL: RWY 09–LOC extending from the 6.6-mile radius to 10 miles west of the airport; and adds an extension within 2 miles each side of the 270° bearing from

the airport extending from the 6.5-mile radius to 10.9 miles west of the airport.

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL MI E5 Gaylord, MI [Amended]

Gaylord Regional Airport, MI
(Lat. 45°00′47″ N, long 84°42′12″ W)
Gaylord RGNL: RWY 09–LOC
(Lat. 45°00′52″ N, long 84°41′15″ W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of the Gaylord Regional Airport; and within 2 miles each side of the 090° bearing from the airport extending from the 6.6-mile radius to 10.5 miles east of the airport; and within 9.5 miles north and 6 miles south of the 270° bearing from the Gaylord RGNL: RWY 09–LOC extending from the 6.6-mile radius to 10 miles west of the airport; and within 2 miles each side of the 270° bearing from the airport extending from the 6.6-mile radius of the airport to 10.9 miles west of the airport.

* * * * *

Issued in Fort Worth, Texas, on December 31, 2024.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2024–31638 Filed 1–6–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–2431; Airspace Docket No. 24–ASW–19]

RIN 2120–AA66

Revocation of Class E Airspace; Follett, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action revokes the Class E airspace at Follett, TX. This action due to the instrument procedures being cancelled at this airport and the airspace is no longer required.

DATES: Effective 0901 UTC, April 17, 2025. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: A copy of the Notice of Proposed Rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at *www.regulations.gov* using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it revokes the Class E airspace extending upward from 700 feet above the surface at Follett/Lipscomb County Airport, Follett, TX, due to the instrument procedures being cancelled and the airspace no longer being required.

History

The FAA published an NPRM for Docket No. FAA–2024–2431 in the **Federal Register** (89 FR 84311; October 22, 2024) proposing to revoke the Class E airspace at Follett, TX. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Incorporation by Reference

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11J, dated July 31, 2024, and effective September 15, 2024. FAA Order JO 7400.11J is publicly available as listed in the **ADDRESSES** section of this

document. These amendments will be published in the next update to FAA Order JO 7400.11.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Differences From the NPRM

Subsequent to publication of the NPRM, a typographic error was discovered in the header of the airspace legal description. ''ASW AR E5 Follett, TX'' should be ''ASW TX E5 Follett, TX'' That error has been corrected in this action.

The Rule

This amendment to 14 CFR part 71 revokes the Class E airspace extending upward from 700 feet above the surface at Follett/Lipscomb County Airport, Follett, TX.

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASW TX E5 Follett, TX [Remove]

* * * * *

Issued in Fort Worth, Texas, on December 31, 2024.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2024–31642 Filed 1–6–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–2429; Airspace Docket No. 24–ASW–18]

RIN 2120–AA66

Amendment of Class E Airspace; El Dorado, AR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace at El Dorado, AR. This action is the result of an airspace review conducted due to the development of new instrument procedures. The geographic coordinates and name of the airport and the name of the El Dorado VOR/DME are also being updated to coincide with the FAA's aeronautical database. This action brings the airspace into compliance with FAA orders and support instrument flight rule (IFR) procedures and operations.

DATES: Effective 0901 UTC, April 17, 2025. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: A copy of the Notice of Proposed Rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at *www.regulations.gov* using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class E surface airspace and Class E airspace extending upward from 700 feet above the surface at South Arkansas Regional Airport at Goodwin Field, El Dorado, AR, to support IFR operations at this airport.

History

The FAA published an NPRM for Docket No. FAA–2024–2429 in the **Federal Register** (89 FR 84309; October 22, 2024) proposing to amend the Class E airspace at El Dorado, AR. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Incorporation by Reference

Class E airspace designations are published in paragraph 6005 of FAA

Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11J, dated July 31, 2024, and effective September 15, 2024. FAA Order JO 7400.11J is publicly available as listed in the **ADDRESSES** section of this document. These amendments will be published in the next update to FAA Order JO 7400.11.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Differences From the NPRM

The airspace legal description of the extension southwest of the airport contained in the Class E airspace extending upward from 700 feet above the surface at South Arkansas Regional Airport at Goodwin Field, El Dorado, AR, is being changed from ''. . . each side of the 229° radial of the El Dorado VOR/DME . . .'' to ''. . . each side of the 236° bearing from the El Dorado VOR/DME . . .'' This change is to address a conflict between the terms radial and bearing and to comply with requirement changes in FAA orders. This change does not change the airspace as proposed in the NPRM thus is incorporated into this action.

The Rule

This amendment to 14 CFR part 71:

Modifies the Class E surface airspace at South Arkansas Regional Airport at Goodwin Field, El Dorado, AR, by updating the name (previously South Arkansas Regional, Goodwin Field) and the geographic coordinates of the airport to coincide with the FAA's aeronautical database; and removes the city associated with the airport in the airspace legal description header to comply with changes to FAA Order JO 7400.2P, Procedures for Handling Airspace Matters;

And modifies the Class E airspace extending upward from 700 feet above the surface at South Arkansas Regional Airport at Goodwin Field by removing the extension east of the airport as it is no longer required; modifies the extension southwest of the airport to within 1.6 miles each side of the 236° bearing (previously radial) from the El Dorado VOR/DME (previously El Dorado VORTAC) extending from the 6.7-mile radius from the airport to 15 miles southwest of the El Dorado VOR/DME (previously the airport); updates the geographic coordinates and name of the airport (previously Goodwin Field) and the name of the El Dorado VOR/DME (previously El Dorado VORTAC) to coincide with the FAA's aeronautical database; and removes the city associated with the airport in the airspace legal description header to comply with changes to FAA Order JO 7400.2P.

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

Paragraph 6002 Class E Airspace Areas Designated as Surface Areas.

* * * * *

ASW AR E2 El Dorado, AR [Amended]

South Arkansas Regional Airport at Goodwin Field, AR
(Lat. 33°13′16″ N, long 92°48′42″ W)

That airspace extending upward from the surface within a 4.2-mile radius of South Arkansas Regional Airport at Goodwin Field.

* * * * *

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASW AR E5 El Dorado, AR [Amended]

South Arkansas Regional Airport at Goodwin Field, AR
(Lat. 33°13′16″ N, long 92°48′42″ W)
El Dorado VOR/DME
(Lat. 33°15′22″ N, long 92°44′38″ W)

That airspace extending upward from 700 feet above the surface within a 6.7-mile radius of South Arkansas Regional Airport at Goodwin Field; and within 1.6 miles each side of the 236° bearing from the El Dorado VOR/DME extending from the 6.7-mile radius of the airport to 15 miles southwest of the El Dorado VOR/DME.

* * * * *

Issued in Fort Worth, Texas, on December 31, 2024.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2024–31641 Filed 1–6–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–2368; Airspace Docket No. 24–ACE–9]

RIN 2120–AA66

Amendment of Class E Airspace; Smith Center, KS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace at Smith Center, KS. This action is the result of an airspace review conducted due to the decommissioning of the Mankato very high frequency omnidirectional range (VOR) as part of the VOR Minimum Operational Network (MON) Program. This action also updates the geographic coordinates of the airport to coincide with the FAA's

aeronautical database. This action brings the airspace into compliance with FAA orders and supports instrument flight rule (IFR) procedures and operations.

DATES: Effective 0901 UTC, April 17, 2025. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: A copy of the Notice of Proposed Rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at *www.regulations.gov* using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class E airspace extending upward from 700 feet above the surface at Smith Center Municipal Airport, Smith Center, KS, to support IFR operations at this airport.

History

The FAA published an NPRM for Docket No. FAA–2024–2368 in the **Federal Register** (89 FR 84308; October 22, 2024) proposing to amend the Class E airspace at Smith Center, KS. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Incorporation by Reference

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11J, dated July 31, 2024, and effective September 15, 2024. FAA Order JO 7400.11J is publicly available as listed in the **ADDRESSES** section of this document. These amendments will be published in the next update to FAA Order JO 7400.11.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 modifies the Class E airspace extending upward from 700 feet above the surface to within a 6.5-mile (increased from a 6.4-mile) radius of Smith Center Municipal Airport, Smith Center, KS; and updates geographic coordinates of the airport to coincide with the FAA's aeronautical database.

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ACE KS E5 Smith Center, KS [Amended]

Smith Center Municipal Airport, KS
(Lat. 39°45′45″ N, 98°47′40″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Smith Center Municipal Airport.

* * * * *

Issued in Fort Worth, Texas, on December 31, 2024.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2024–31640 Filed 1–6–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–2366; Airspace Docket No. 24–AGL–24]

RIN 2120–AA66

Amendment of Class E Airspace; Pontiac, IL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace at Pontiac, IL. This action is the result of an airspace review conducted due to the decommissioning of the Pontiac very high frequency omnidirectional range (VOR) as part of the VOR Minimum Operational Network (MON) Program. The geographic coordinates of the airport are also being updated to coincide with the FAA's aeronautical database. This action brings the airspace into compliance with FAA orders and supports instrument flight rule (IFR) procedures and operations.

DATES: Effective 0901 UTC, April 17, 2025. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: A copy of the Notice of Proposed Rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at *www.regulations.gov* using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class E airspace extending upward from 700 feet above the surface at Pontiac Municipal Airport, Pontiac, IL, to support IFR operations at this airport.

History

The FAA published an NPRM for Docket No. FAA–2024–2366 in the **Federal Register** (89 FR 84307; October 22, 2024) proposing to amend the Class E airspace at Pontiac, IL. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Incorporation by Reference

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11J, dated July 31, 2024, and effective September 15, 2024. FAA Order JO 7400.11J is publicly available as listed in the **ADDRESSES** section of this document. These amendments will be published in the next update to FAA Order JO 7400.11.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 modifies the Class E airspace extending upward from 700 feet above the surface to within a 6.8-mile (reduced from a 7.2-mile) radius of Pontiac Municipal Airport, Pontiac, IL; and updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL IL E5 Pontiac, IL [Amended]

Pontiac Municipal Airport, IL
(Lat. 40°55′28″ N, long 88°37′26″ W)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of the Pontiac Municipal Airport.

* * * * *

Issued in Fort Worth, Texas, on December 31, 2024.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2024–31639 Filed 1–6–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 100 and 165

[USCG–2022–0709]

2021 3rd Quarter Listings; Safety Zones, Security Zones, and Special Local Regulations

AGENCY: Coast Guard, DHS.

ACTION: Notification of expired temporary rules issued.

SUMMARY: This document provides notification of substantive rules issued by the Coast Guard that were made temporarily effective but expired before they could be published in the **Federal Register**. This document lists temporary safety zones, security zones, and special local regulations, all of limited duration and for which timely publication in the **Federal Register** was not possible. This document also announces notifications of enforcement for existing reoccurring regulations that we issued but were unable to be published before the enforcement period ended.

DATES: This document lists temporary Coast Guard rules and notifications of enforcement that became effective, primarily between July 2021 and September 2021, and expired before they could be published in the **Federal Register**.

ADDRESSES: Temporary rules listed in this document may be viewed online, under their respective docket numbers, using the Federal eRulemaking Portal at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For questions on this document contact Ambar Ali, Office of Regulations and Administrative Law, telephone (202) 372–3862.

SUPPLEMENTARY INFORMATION: Coast Guard District Commanders and Captains of the Port (COTP) must be immediately responsive to the safety and security needs within their jurisdiction; therefore, District Commanders and COTPs have been delegated the authority to issue certain local regulations. *Safety zones* may be established for safety or environmental purposes. A safety zone may be stationary and described by fixed limits or it may be described as a zone around a vessel in motion. *Security zones* limit access to prevent injury or damage to vessels, ports, or waterfront facilities. *Special local regulations* are issued to enhance the safety of participants and spectators at regattas and other marine events.

Timely publication of these rules in the **Federal Register** may be precluded when a rule responds to an emergency, or when an event occurs without sufficient advance notice. The affected public is, however, often informed of these rules through Local Notices to Mariners, press releases, and other means. Moreover, actual notification is provided by Coast Guard patrol vessels enforcing the restrictions imposed by the rule. Timely publication of notifications of enforcement of reoccurring regulations may be precluded when the event occurs with short notice or other agency procedural restraints.

Because **Federal Register** publication was not possible before the end of the effective period, mariners would have been personally notified of the contents of these safety zones, security zones, special local regulations, regulated navigation areas or drawbridge operation regulations by Coast Guard officials on-scene prior to any enforcement action. However, the Coast Guard, by law, must publish in the **Federal Register** notice of substantive rules adopted. To meet this obligation without imposing undue expense on the public, the Coast Guard periodically publishes a list of these temporary safety zones, security zones, special local regulations, regulated navigation areas and drawbridge operation regulations. Permanent rules are not included in this list because they are published in their entirety in the **Federal Register**. Temporary rules are also published in their entirety if sufficient time is available to do so before they are placed in effect or terminated. In some of our reoccurring regulations, we say we will publish a notice of enforcement as one of the means of notifying the public. We use this notification to announce those notifications of enforcement that we issued and will post them to their dockets.

The following unpublished rules were placed in effect temporarily during the period between July 2021 and September 2021. To view copies of these rules, visit *www.regulations.gov* and search by the docket number indicated in the following table.

Docket No.	Type of regulation	Location	Enforcement date
USCG–2021–0513	Security Zones (Part 165)	Surfside, FL	7/1/2021
USCG–2021–0267	Special Local Regulations (Part 100) and Safety Zones (Parts 147 and 165).	Long Island Sound Captain of the Port Zone	7/1/2021
USCG–2021–0465	Safety Zones (Parts 147 and 165)	Rockland, ME	7/2/2021
USCG–2021–0518	Safety Zones (Parts 147 and 165)	Alton, MO	7/3/2021
USCG–2021–0314	Safety Zones (Parts 147 and 165)	St. Michaels, MD	7/3/2021
USCG–2021–0393	Safety Zones (Parts 147 and 165)	Captain of the Port Buffalo Zone	7/3/2021
USCG–2021–0443	Safety Zones (Parts 147 and 165)	Sector Columbia River Captain of the Port Zone.	7/3/2021
USCG–2021–0202	Special Local Regulations (Part 100)	Chesapeake City, MD	7/4/2021
USCG–2021–0535	Safety Zones (Parts 147 and 165)	Detroit, MI	7/9/2021
USCG–2021–0522	Safety Zones (Parts 147 and 165)	Port Fourchon, LA	7/9/2021
USCG–2021–0523	Safety Zones (Parts 147 and 165)	Cocodrie, LA	7/10/2021
USCG–2021–0539	Safety Zones (Parts 147 and 165)	Tampa, FL	7/12/2021
USCG–2021–0491	Safety Zones (Parts 147 and 165)	Strait of Juan De Fuca, WA	7/12/2021
USCG–2021–0529	Safety Zones (Parts 147 and 165)	Naval Exercise Area, WA	7/13/2021
USCG–2021–0261	Safety Zones (Parts 147 and 165)	Essexville, MI	7/14/2021
USCG–2021–0478	Safety Zones (Parts 147 and 165)	Wilmington, NC	7/16/2021
USCG–2021–0548	Safety Zones (Parts 147 and 165)	Chicago, IL	7/17/2021
USCG–2021–0551	Special Local Regulations (Part 100)	Eastlake, OH	7/17/2021
USCG–2021–0543	Special Local Regulations (Part 100)	Wyandotte, MI	7/17/2021
USCG–2021–0567	Security Zones (Part 165)	Cincinnati, OH	7/21/2021
USCG–2021–0571	Security Zones (Part 165)	Cincinnati, OH	7/21/2021
USCG–2021–0113	Special Local Regulations (Part 100)	Kennewick, WA	7/23/2021
USCG–2021–0566	Safety Zones (Parts 147 and 165)	Bratenahl, OH	7/24/2021

Docket No.	Type of regulation	Location	Enforcement date
USCG–2021–0572	Safety Zones (Parts 147 and 165)	Madison Township, OH	7/24/2021
USCG–2021–0577	Safety Zones (Parts 147 and 165)	Corpus Christi, TX	7/24/2021
USCG–2021–0587	Safety Zones (Parts 147 and 165)	Seal Beach, CA	7/24/2021
USCG–2021–0065	Safety Zones (Parts 147 and 165)	Cleveland, OH	7/24/2021
USCG–2021–0578	Safety Zones (Parts 147 and 165)	Ingleside, TX	7/25/2021
USCG–2021–0593	Safety Zones (Parts 147 and 165)	Chicago, IL	7/26/2021
USCG–2021–0541	Special Local Regulations (Part 100)	Oak Harbor, WA	7/31/2021
USCG–2021–0330	Safety Zones (Parts 147 and 165)	Atlantic City, NJ	8/1/2021
USCG–2021–0394	Safety Zones (Parts 147 and 165)	Bath, ME	8/1/2021
USCG–2021–0581	Security Zones (Part 165)	Rehoboth Beach, DE	8/6/2021
USCG–2021–0561	Safety Zones (Parts 147 and 165)	Michigan City, IN	8/7/2021
USCG–2021–0621	Safety Zones (Parts 147 and 165)	Detroit, MI	8/14/2021
USCG–2021–0559	Safety Zones (Parts 147 and 165)	Stillwater, MN	8/14/2021
USCG–2021–0645	Special Local Regulations (Part 100)	Perry, WA	8/14/2021
USCG–2021–0683	Safety Zones (Parts 147 and 165)	Chicago, IL	8/21/2021
USCG–2021–0531	Safety Zones (Parts 147 and 165)	Maidsville, WV	8/23/2021
USCG–2021–0068	Safety Zones (Parts 147 and 165)	Port Arthur Captain of the Port Zone	8/26/2021
USCG–2021–0067	Safety Zones (Parts 147 and 165)	Cameron Parish, LA	8/27/2021
USCG–2021–0665	Safety Zones (Parts 147 and 165)	Washington, NC	8/27/2021
USCG–2021–0705	Safety Zones (Parts 147 and 165)	Lower Mississippi River, LA	8/27/2021
USCG–2021–0689	Safety Zones (Parts 147 and 165)	Chicago, IL	8/29/2021
USCG–2021–0709	Safety Zones (Parts 147 and 165)	Lower Mississippi River, LA	8/31/2021
USCG–2021–0712	Safety Zones (Parts 147 and 165)	Cameron Parish, LA	9/3/2021
USCG–2021–0695	Safety Zones (Parts 147 and 165)	Glencoe, IL	9/3/2021
USCG–2021–0682	Safety Zones (Parts 147 and 165)	Lakeside, OH	9/4/2021
USCG–2021–0687	Security Zones (Part 165)	Boston, MA	9/9/2021
USCG–2021–0688	Security Zones (Part 165)	Boston, MA	9/11/2021
USCG–2021–0725	Safety Zones (Parts 147 and 165)	Chicago, IL	9/11/2021
USCG–2021–0660	Safety Zones (Parts 147 and 165)	Coraopolis, PA	9/11/2021
USCG–2021–0637	Safety Zones (Parts 147 and 165)	Frankfort Harbor, MI	9/12/2021
USCG–2021–0128	Safety Zones (Parts 147 and 165)	Virginia Beach, VA	9/12/2021
USCG–2021–0127	Safety Zones (Parts 147 and 165)	Potomac River, Between Charles Count, MD and King George County, VA.	9/13/2021
USCG–2021–0693	Safety Zones (Parts 147 and 165)	Cleveland, OH	9/18/2021
USCG–2021–0759	Safety Zones (Parts 147 and 165)	Corpus Christi, TX	9/22/2021
USCG–2021–0764	Safety Zones (Parts 147 and 165)	Corpus Christi, TX	9/23/2021
USCG–2021–0670	Safety Zones (Parts 147 and 165)	Toledo, OH	9/23/2021

Michael Cunningham,

Chief, Office of Regulations and Administrative Law.

[FR Doc. 2024–31658 Filed 1–6–25; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–1095]

RIN 1625–AA00

Safety Zone; Cypress Passage Overhead Powerline Demolition and Removal, Atchafalaya River, LA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within a 500-yard radius of 29°47′38.18″ N, 91°21′50.52″ W, approximately MM 105.5, on the Atchafalaya River, locally known as Cypress Passage, during an overhead electrical powerline structure demolition operation on Thursday, January 9, 2025. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by the demolition of the powerline structures resulting in electrical powerlines on the navigational water's surface. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Marine Safety Unit Houma.

DATES: This rule is effective from 8 a.m. Central Standard Time (CST) on Thursday, January 9, 2025, through 8 p.m. CST on Thursday, January 9, 2025.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2024–1095 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 LCDR Justin Kimrey at telephone (985) 665–2449 or email *d08-smb-msuhouma-waterways@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
CST Central Standard Time
DHS Department of Homeland Security
FR Federal Register
MM Mile Marker
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 under the authority in 5 U.S.C. 553(b)(B). This statutory 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.'' The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because during the 12-hour overhead electrical powerline structure demolition the

electrical powerlines will be on top of the navigational water's surface, crossing the navigational channel and posing potential safety hazards to passing vessels. It is impracticable to publish an NPRM because we must establish this safety zone by January 9, 2025.

Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because prompt action is needed to respond to the potential safety hazards associated with electrical powerlines crossing the navigational channel.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Houma (COTP) has determined that potential hazards associated with the Cypress Passage overhead powerline demolition and removal occurring on January 9, 2025, will be a safety concern for anyone within a 500-yard radius of 29°47′38.18″ N, 91°21′50.52″ W, approximately MM 105.5 on the Atchafalaya River, locally known as Cypress Passage. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the electrical power lines are being removed from the navigational channel.

IV. Discussion of the Rule

This rule establishes a safety zone from 8 a.m. through 8 p.m. on Thursday January 9, 2024. The safety zone will cover all navigable waters within a 500-yard radius of 29°47′38.18″ N, 91°21′50.52″ W, approximately MM 105.5 on the Atchafalaya River, locally known as Cypress Passage. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while electrical power lines are being removed from the navigational water's surface during the demolition of overhead powerline structures along the navigational channel. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or the COTP's designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under 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-day of the safety zone. Vessel traffic will not be able to safely transit around this safety zone which would impact this designated area of the Atchafalaya River for 12 hours. The Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow 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 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 lasting only 12 hours that will prohibit entry within a 500-yard radius of the demolition site of overhead electrical powerlines that will cross the navigational water's surface. 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.

Accordingly, 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.T08–1095 to read as follows:

§ 165.T08–1095 Safety Zone; Cypress Passage overhead powerline demolition and removal, Atchafalaya River, LA.

(a) *Location.* The following area is a safety zone: All waters of the Atchafalaya River, locally known as Cypress Passage, from surface to bottom, within a 500-yard radius of 29°47′38.18″ N, 91°21′50.52″ W, approximately MM 105.5, during an overhead electrical powerline structure demolition operation from 8 a.m. CST on Thursday January 9, 2025 through 8 p.m. CST on Thursday January 9, 2025.

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

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

(2) To seek permission to enter, contact the COTP or the COTP's representative by hailing on VHF radio channels 13 or 16. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced from 8 a.m. CST on Thursday January 9, 2025, through 8 p.m. CST on Thursday January 9, 2025.

Dated: December 31, 2024.

Jason S. Franz,

Captain, U.S. Coast Guard, Captain of the Port Marine Safety Unit Houma.

[FR Doc. 2024–31671 Filed 1–6–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2024–1094]

RIN 1625–AA87

Security Zone; Potomac River and Anacostia River, and Adjacent Waters; Washington, DC

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a security zone along the Potomac and Anacostia Rivers and adjacent waters at Washington, DC to protect government officials, mitigate potential terrorist acts, and enhance public and maritime safety and security in the days leading up to and after the 60th Presidential Inauguration. During the enforcement period, entry into or remaining within the security zone is prohibited unless authorized by the Captain of the Port or his designated representative.

DATES: The regulations in 33 CFR 165.508 will be enforced from 8 a.m. on January 18, 2025, through 11:59 p.m. on January 21, 2025, for the security zone identified in 33 CFR 165.508(a)(6).

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email LCDR Kate Newkirk, Sector Maryland-NCR, Waterways Management Division, U.S. Coast Guard; 410–365–8141, *MDNCRWaterways@uscg.mil.*

SUPPLEMENTARY INFORMATION: On October 2, 2024, the Coast Guard was notified by the event organizer that the anticipated dates for the activities associated with the 60th Presidential Inauguration are scheduled from January 18, 2025, to January 21, 2025. The Coast Guard will enforce regulations in 33 CFR 165.508 for the zone identified in paragraph (a)(6). This action is being taken to protect government officials, mitigate potential terrorist acts and incidents, and enhance public and maritime safety and security immediately before, during, and after this event. Thirty-three CFR 165.508(d)(4) provides that the security zone will be enforced from 8 a.m. on January 18, 2025, until 11:59 p.m. on January 21, 2025. Subsection (d)(1) of § 165.508 also provides that the security zone will be enforced, in addition to the specified times in paragraphs (d)(4) of that section, upon issuance of a notice of enforcement by the Captain of the Port Maryland-National Capital Region.

Our regulation entitled ''Security Zone; Potomac River and Anacostia River, and adjacent waters; Washington, DC,'' § 165.508, specifies the location for this security zone as an area that includes all navigable waters described in paragraphs (a)(1) through (a)(3). This security zone includes: (1) the area comprising Zone 1, all navigable waters of the Potomac River, from shoreline to shoreline, bounded to the north by the Francis Scott Key (US–29) Bridge, at mile 113, and bounded to the south by a line drawn from the Virginia shoreline at Ronald Reagan Washington National Airport, at 38°51′21.3″ N, 077°02′00.0″ W, eastward across the Potomac River to the District of Columbia shoreline at Hains Point at position 38°51′24.3″ N, 077°01′19.8″ W, including the waters of the Boundary Channel, Pentagon Lagoon, Georgetown Channel Tidal Basin, and Roaches Run; (2) the area comprising Zone 2, all navigable waters of the Anacostia River, from shoreline to shoreline, bounded to the north by the John Philip Sousa (Pennsylvania Avenue) Bridge, at mile 2.9, and bounded to the south by a line drawn from the District of Columbia shoreline at Hains Point at position 38°51′24.3″ N, 077°01′19.8″ W, southward across the Anacostia River to the District of Columbia shoreline at Giesboro Point at

position 38°50′52.4″ N, 077°01′10.9″ W, including the waters of the Washington Channel; (3) the area comprising Zone 3, all navigable waters of the Potomac River, from shoreline to shoreline, bounded to the north by a line drawn from the Virginia shoreline at Ronald Reagan Washington National Airport, at 38°51′21.3″ N, 077°02′00.0″ W, eastward across the Potomac River to the District of Columbia shoreline at Hains Point at position 38°51′24.3″ N, 077°01′19.8″ W, thence southward across the Anacostia River to the District of Columbia shoreline at Giesboro Point at position 38°50′52.4″ N, 077°01′10.9″ W, and bounded to the south by the Woodrow Wilson Memorial (I–95/I–495) Bridge, at mile 103.8.

As specified in § 165.508 (b), during the enforcement period, entry into or remaining in the zone is prohibited unless authorized by the Coast Guard Captain of the Port Maryland-National Capital Region. Public vessels and vessels already at berth at the time the security zone is implemented do not have to depart the security zone. All vessels underway within the security zone at the time it is implemented are to depart the zone at the time the security zone is implemented. To seek permission to transit the zone, the Captain of the Port Maryland-National Capital Region can be contacted at telephone number (410) 576–2693 or on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). Coast Guard vessels enforcing this zone can be contacted on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). The Coast Guard may be assisted by other Federal, state or local law enforcement agencies in enforcing this regulation. If the Captain of the Port or his designated on-scene patrol personnel determines the security zone need not be enforced for the full duration stated in this notice, a Broadcast Notice to Mariners may be used to suspend enforcement and grant general permission to enter the security zone.

This notification of enforcement is issued under authority of 33 CFR 165.508 and 5 U.S.C. 552(a). In addition to this notification of enforcement in the **Federal Register**, the Coast Guard will provide notification of this enforcement period via the Local Notice to Mariners and marine information broadcasts.

Dated: January 2, 2025.

Patrick C. Burkett,

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

[FR Doc. 2025–00013 Filed 1–6–25; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2023–0330; FRL–4908.3–02–OAR]

Review of Final Rule Reclassification of Major Sources as Area Sources Under Section 112 of the Clean Air Act; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: The Environmental Protection Agency (EPA) is making corrections to the Review of Final Rule Reclassification of Major Sources as Area Sources Under Section 112 of the Clean Air Act (CAA) final rule that appeared in the **Federal Register** on September 10, 2024. Following publication of this final rule, the EPA discovered an inadvertent typographical error in the regulatory text and is correcting the error in this action.

DATES: The final rule is effective on January 7, 2025.

ADDRESSES: The EPA has established a docket for this rulemaking under Docket ID No. EPA–HQ–OAR–2023–0330. 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 (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov/.*

FOR FURTHER INFORMATION CONTACT: Mr. John Kennedy, Mail Drop: D243–02, 109 T.W. Alexander Drive, P.O. Box 12055, RTP, North Carolina 27711; telephone number: (919) 541–1548; and email address: *kennedy.john@epa.gov.*

I. Summary of Final Action

The EPA is making a correction to the Review of Final Rule Reclassification of Major Sources as Area Sources Under Section 112 of the Clean Air Act (CAA) final rule that appeared in the **Federal Register** on September 10, 2024 (89 FR 73293). In the September 10, 2024, final rule, the EPA amended 40 CFR 63.1(c)(6) to include a requirement that sources subject to certain major source NESHAP used to meet the Agency's obligations under the CAA for seven specific persistent and bioaccumulative pollutants must remain subject to those NESHAP even if the sources reclassify to area source status.

Following publication of this final rule, the EPA discovered an inadvertent typographical error in the regulatory text in 40 CFR 63.1(c)(6) and is correcting the error in this action. Specifically, as finalized on September 10, 2024, the regulatory text in 40 CFR 63.1(c)(6)(iii) included a reference to 40 CFR part 63 subpart HHH (National Emission Standards for Hazardous Air Pollutants from Natural Gas Transmission and Storage Facilities) instead of the correct reference, 40 CFR part 63 subpart MMM (National Emission Standards for Hazardous Air Pollutants for Pesticide Active Ingredient Production). This error was included in the table of CAA 112(c)(6) categories placed in the docket for the Review of Final Rule Reclassification of Major Sources as Area Sources Under Section 112 of the Clean Air Act (docket ID: EPA–HQ–OAR–2023–0330–0033). The table included the correct source category rule name, National Emission Standards for Hazardous Air Pollutants for Pesticide Active Ingredient Production, but instead of referencing the correct regulation reference to 40 CFR part 63 subpart MMM, it referenced 40 CFR part 63 subpart HHH. This error found in the table included in the docket was cross referenced in the regulatory text of the final rulemaking. This action corrects this inadvertent typographical error by removing the reference to 40 CFR part 63 subpart HHH from 40 CFR 63.1(c)(6)(iii) and adding the correct reference to 40 CFR part 63 subpart MMM.

II. Rulemaking Procedures

The EPA's authority for the rulemaking procedures followed in this action is provided by the Administrative Procedure Act (APA), 5 U.S.C. 553. In general, an agency issuing a rule must provide prior notice and an opportunity for public comment, but APA section 553(b)(B) includes an exemption from notice-and-comment requirements ''when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' This action is being issued without prior notice or opportunity for public comment because the EPA finds that the APA ''good cause'' exemption from notice-and-comment requirements applies here.

Following notice-and-comment procedures is unnecessary for this action. This action corrects a

typographical error to correct a reference in 40 CFR 63.1(c)(6)(iii) to 40 CFR part 63 subpart MMM instead of 40 CFR part 63 subpart HHH. It is critical to timely correct the identified error to avoid confusion.

This action is effective immediately upon publication. The APA typically requires publication of a final rule to precede its effective date by at least 30 days unless, as relevant here, the agency finds good cause to make the rule effective sooner. APA section 553(b)(B). Under APA section 553(d), these technical corrections are both necessary and beneficial to regulated entities in understanding and complying with the final rule's requirements. Further, because this rule does not impose any new regulatory requirements, the regulated community does not need time to prepare for it to come into effect. *See Omnipoint Corp.* v. *Fed. Commc'n Comm'n,* 78 F.3d 620, 630 (D.C. Cir. 1996) (in determining whether good cause exists to make a rule immediately effective, an agency should ''balance the necessity for immediate implementation against principles of fundamental fairness which require that all affected persons be afforded a reasonable amount of time to prepare for the effective date of its ruling'').

Good cause exists for this rule to be made immediately effective. The EPA has balanced the necessity for immediate implementation against the benefits of delaying implementation. Because this rule makes a typographical correction to a rule that has already been promulgated, the public is aware of the content of the rule. Making the corrections effective immediately will make the regulatory text consistent with what the proposed rule and the preamble to the final rule have described.

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practices and procedures, Air pollution control, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Michael S. Regan,

Administrator.

For the reasons set forth in the preamble, the Environmental Protection Agency is amending title 40, chapter I, part 63 of the Code of Federal Regulations as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

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

Subpart A—General Provisions

■ 2. Amend § 63.1 by revising paragraph (c)(6)(iii) as follows:

§ 63.1 Applicability.

* * * * *

(c) * * *

(6) * * *

(iii) After September 10, 2024, affected sources subject to the following 40 CFR part 63 subparts on September 10, 2024, must remain subject to those subparts, and any modifications thereafter, even if the source becomes an area source by reducing both its actual emissions and potential to emit hazardous air pollutants to below major source thresholds: F, G, H, I, L, R, X, CC, GG, II, JJ, KK, LL, MM, EEE, JJJ, LLL, MMM, RRR, UUU, FFFF, JJJJ, MMMM, PPPP, ZZZZ, CCCCC, DDDDD, FFFFF, IIIII, LLLLL, YYYYY, JJJJJJ, EEEEEEE.

* * * * *

[FR Doc. 2024–31226 Filed 1–6–25; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2005–0155; FRL–8391–01–OAR]

RIN 2060–AV44

National Emission Standards for Hazardous Air Pollutants: National Perchloroethylene Air Emission Standards for Dry Cleaning Facilities Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final determination.

SUMMARY: This action finalizes the Clean Air Act (CAA) technology review (TR) conducted for the commercial and industrial dry cleaning facilities using perchloroethylene (PCE) as the cleaning solvent (PCE Dry Cleaning) source categories regulated under National Emission Standards for Hazardous air Pollutants (NESHAP). This final rule does not finalize the changes made at proposal and makes no amendments to the current NESHAP given the recently finalized action under the Toxic Substance Control Act (TSCA) which has instituted a 10-year phaseout of the use of PCE for dry cleaning.

DATES: This action is effective on January 7, 2024.

ADDRESSES: The U.S. Environmental Protection Agency (EPA) has established a docket for this action under Docket ID No. EPA–HQ–OAR–2005–0155. 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: Reginald Goodwin, Mail Drop: D243–04, 109 T.W. Alexander Drive, P.O. Box 12055, RTP, North Carolina 27711; telephone number: (919) 541–5313; and email address: *goodwin.reginald@epa.gov.*

SUPPLEMENTARY INFORMATION:

Preamble acronyms and abbreviations. Throughout this notice the use of ''we,'' ''us,'' or ''our'' is intended to refer to the EPA. 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:

CAA Clean Air Act
CFR Code of Federal Regulations
EPA U.S. Environmental Protection Agency
FR Federal Register
GACT generally available control technology
HAP hazardous air pollutants(s)
LDAR leak detection and repair
MACT maximum achievable control technology
NAICS North American Industry Classification System
NESHAP National Emission Standards for Hazardous Air Pollutants
NTTAA National Technology Transfer and Advancement Act

OCSPP Office of Chemical Safety and Pollution Prevention
OMB Office of Management and Budget
PCE perchloroethylene
PRA Paperwork Reduction Act
RFA Regulatory Flexibility Act
tpy tons per year
TR technology review
TSCA Toxic Substance Control Act
UMRA Unfunded Mandates Reform Act

Background information. On December 27, 2021, the EPA proposed revisions to the National Perchloroethylene Air Emission Standards for Dry Cleaning Facilities NESHAP (hereafter referred to as the PCE Dry Cleaning NESHAP) based on our technology review (TR). In this action, we are finalizing decisions 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 the *Response to Comments National Perchloroethylene Air Emissions Standards for Dry Cleaning Facilities* document, which is available in the Docket for this rulemaking (Docket ID No. EPA–HQ–OAR–2005–0155).

Organization of this document. The information in this preamble is organized as follows:

I. General Information
A. Does this action apply to me?
B. Where can I get a copy of this document and other related information?
C. Judicial Review and Administrative Reconsideration
II. Background
A. What is the statutory authority for this action?
B. What are the PCE Dry Cleaning source categories and how does the NESHAP regulate HAP emissions from these source categories?
C. What changes did we propose for the PCE Dry Cleaning NESHAP in our December 27, 2021, proposal?
III. What is included in this final rule?
A. What are the final rule amendments based on the technology review for the PCE Dry Cleaning NESHAP?
IV. What is the rationale for our final decisions and amendments for the PCE Dry Cleaning NESHAP?
A. Technology Review for the PCE Dry Cleaning NESHAP
V. Summary of Cost, Environmental, and Economic Impacts and Additional Analyses Conducted
A. What are the affected facilities?
B. What are the air quality, cost, economic impacts, and benefits?
C. What analysis of environmental justice did we conduct?
D. What analysis of children's environmental health did we conduct?
VI. Statutory and Executive Order Reviews
A. Executive Orders 12866: Regulatory Planning and Review, Executive Order 13563: Improving Regulation and Regulatory Review, and Executive Order 14094: Modernizing Regulatory Review
B. Paperwork Reduction Act (PRA)
C. Regulatory Flexibility Act (RFA)
D. Unfunded Mandates Reform Act (UMRA)
E. Executive Order 13132: Federalism
F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act (NTTAA)
J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations
K. Congressional Review Act (CRA)

I. General Information

A. Does this action apply to me?

Regulated entities. Categories and entities potentially regulated by this action are shown in table 1 of this preamble.

TABLE 1—NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS FINAL RULE

Source Category and NESHAP	NAICS code [1]
Dry Cleaning	812310, 812320, 812332

[1] North American Industry Classification System (NAICS).

This list of categories and NAICS codes is not intended to be exhaustive, but rather provides a guide for readers regarding the entities likely to be affected by the final action for the source categories 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 person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this preamble.

B. 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/dry-cleaning-facilities-national-perchloroethylene-air-emission.* 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.

C. 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 March 10, 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 section 112 of the Clean Air Act (CAA), as amended (42 U.S.C. 7401 *et seq.*). Section 112 of the CAA establishes a two-stage regulatory process to develop standards for emissions of hazardous air pollutants (HAP) from stationary sources. Generally, the first stage involves establishing technology-based standards and the second stage involves evaluating those standards that are based on maximum achievable control technology (MACT) to determine whether additional standards are needed to address any remaining risk associated with HAP emissions. This second stage is commonly referred to as the ''residual risk review.'' In addition to the residual risk review, the CAA also requires the EPA to review standards set under CAA section 112 every 8 years and revise the standards as necessary taking into account developments in practices, processes, or control technologies. This review is commonly referred to as the ''technology review,'' and is the subject of this final rule. The discussion that follows identifies the most relevant statutory sections and briefly explains the contours of the methodology used to implement these statutory requirements.

In the first stage of the CAA section 112 standard setting process, the EPA promulgates technology-based standards under CAA section 112(d) for categories of sources identified as emitting one or more of the HAP listed in CAA section 112(b). 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 10 tons per year (tpy) or more of a single HAP or 25 tpy or more of any combination of HAP. All other sources are ''area sources.'' For major sources, CAA section 112(d)(2) provides that the technology-based NESHAP must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). These standards are commonly referred to as MACT standards. CAA section 112(d)(3) also establishes a minimum control level for MACT standards, known as the MACT ''floor.'' In certain instances, as provided in CAA section 112(h), the EPA may set work practice standards in lieu of numerical emission standards. The EPA must also consider control options that are more stringent than the floor. Standards more stringent than the floor are commonly referred to as ''beyond-the-floor'' standards. For area sources, CAA section 112(d)(5) allows the EPA to set standards based on generally available control technologies or management practices (GACT standards) standards 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) and concurrently conducting a TR pursuant to CAA section 112(d)(6). For categories of area sources subject to GACT standards, there is no requirement to address residual risk, but, similar to the major source categories, the TR is required.

CAA section 112(d)(6) requires the EPA to review standards promulgated under CAA section 112 and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less often than every 8 years. In conducting this review, which we call the ''technology 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).

B. What are the PCE Dry Cleaning source categories and how does the NESHAP regulate HAP emissions from these source categories?

The EPA promulgated the PCE Dry Cleaning NESHAP on September 22, 1993 (58 FR 49376), as 40 CFR part 63, subpart M. Significant amendments were promulgated on June 3, 1996 (61 FR 27788), December 14, 1999 (64 FR 69643), July 27, 2006 (71 FR 42743), and July 11, 2008 (73 FR 39871). The PCE Dry Cleaning NESHAP includes MACT standards which apply to major sources, and GACT standards which apply to area sources of dry cleaning that use the chemical PCE. The PCE Dry Cleaning NESHAP regulates PCE emitted from the dry cleaning process. The source categories covered by these MACT and GACT standards currently include all PCE dry cleaning facilities in the U.S.

Dry cleaning is any cleaning process for clothing using a solvent other than water. Perchloroethylene (PCE), also known as perc, tetrachloroethene and tetrachloroethylene, is widely used in the industry. Establishments may also offer specialty cleaning services for garments and textiles. The 1993 NESHAP exempted coin-operated dry cleaning machines.

There are two types of PCE dry cleaning machines: transfer and dry-to-dry. Similar to residential washing machines and dryers, transfer machines include a unit for washing and another unit for drying. Following the wash cycle, PCE-containing articles are manually transferred from the washer to the dryer. The transfer of wet fabrics is the predominant source of PCE emissions in these systems.

1. Transfer Machines (First Generation)

Transfer machines are prohibited at all existing and new major and area sources due to the NESHAP's requirement that dry cleaning systems eliminate any emissions of PCE while transferring articles between the washer and the dryer or reclaimer. Therefore, transfer machines are no longer sold, and none are known to still be in operation as these machines have reached the end of their useful lives and should have been replaced by dry-to-dry machines.

2. Dry-to-Dry Machines (Second, Third, Fourth and Fifth Generation)

Dry-to-dry machines wash, extract, and dry the articles in a single machine. Eliminating the transfer step results in much lower emissions.

a. ''Second generation'' dry-to-dry machines were vented to the atmosphere from the machine-washing drum at the time that the machine is opened following the drying cycle.

b. ''Third generation'' dry-to-dry machines operated the first ''closed-loop'' machines. This is the first generation where emissions were routed to a refrigerated condenser.

c. ''Fourth generation'' dry-to-dry machines (technology from the early 1990s) are closed-loop systems using the secondary controls refrigerated condenser(s) and a carbon adsorption unit(s). The condenser is a vapor recovery system, condensing PCE by cooling the gas-vapor stream. The air remaining at the end of the cycle passes

through a carbon adsorber—a bed of activated carbon into which the air-PCE gas-vapor stream is routed—that removes PCE from the gas-vapor stream prior to door opening. The implementation of both the condenser and adsorber offers greater emissions reductions over a dry-to-dry machine with only a refrigerated condenser, reducing PCE concentration in the air remaining in the machine once the cleaning cycle is complete instead of allowing ventilation or release at the end of the dry cleaning cycle.

d. ''Fifth generation'' machines (technology from the late 1990s) have the same control technology as fourth generation machines, but are also equipped with an inductive fan, internal solvent vapor monitoring devices (sensor) and interlock (lockout) devices not allowing access to the machine until solvent vapor concentrations are below 300 ppm.

Per 40 CFR 63.320, a dry cleaning facility is a major source if the facility emits or has the potential to emit more than 10 tons per year of PCE to the atmosphere. A dry cleaning facility is considered an area source if it does not meet the criteria for major sources, as specified in 40 CFR 63.320. However, in lieu of measuring or determining a facility's potential to emit PCE emissions, a dry cleaning facility is a major source if: (1) it includes only dry-to-dry machine(s) and has a total yearly PCE consumption greater than 2,100 gallons as determined according to 40 CFR 63.323(d); or (2) it includes only transfer machine system(s) or both dry-to-dry machine(s) and transfer machine system(s) and has a total yearly PCE consumption greater than 1,800 gallons as determined according to 40 CFR 63.323(d). As defined by the initial list of source categories published on July 16, 1992 (57 FR 31576), the PCE Dry Cleaning NESHAP applies to the following major and area sources of HAP emissions:

Major Source Categories

- Commercial Dry Cleaning [Perchloroethylene]—Transfer Machines
- Industrial Dry Cleaning [Perchloroethylene]—Transfer Machines
- Industrial Dry Cleaning [Perchloroethylene]—Dry-to-Dry Machines

Area Source Categories

- Commercial Dry Cleaning [Perchloroethylene]—Transfer Machines
- Commercial Dry Cleaning [Perchloroethylene]—Dry-to-Dry Machines

In general, the PCE Dry Cleaning NESHAP affects three types of dry cleaners that use PCE: commercial, industrial, and co-residential. Commercial facilities clean household items such as suits, dresses, coats, pants, comforters, curtains, leather clothing, and formal wear. Industrial dry cleaners clean heavily stained articles such as work gloves, uniforms, mechanics' overalls, mops, and shop rags. Co-residential facilities were a subset of commercial operations and included dry cleaning operations located in buildings in which people reside. Co-residential facilities were generally found in urban areas where commercial and residential occupancy occur in a single building, but these facilities are no longer allowed to operate based on the NESHAP requirements.

The PCE Dry Cleaning NESHAP identifies all major sources as ''large'' industrial and commercial dry cleaners. These dry cleaners are subject to MACT standards under this NESHAP. It is estimated that there are five or fewer of these major source dry cleaners remaining in the United States.[1] The PCE Dry Cleaning NESHAP requires *new* major source PCE dry cleaners operating dry-to-dry machines to:

- Operate with a refrigerated condenser and carbon adsorber process controls.
- Use an enhanced leak detection and repair (LDAR) program to detect PCE leaks from the machines (*i.e.,* PCE gas analyzer operated according to EPA Method 21), repair the leaks, and maintain records.

The PCE Dry Cleaning NESHAP requires *existing* major source PCE dry cleaners operating dry-to-dry machines to:

- Operate with a refrigerated condenser or a carbon adsorber as process control.
- Use an enhanced leak detection and repair (LDAR) program to detect PCE leaks from the machines (*i.e.,* PCE gas analyzer operated according to EPA Method 21), repair the leaks, and maintain records.

Dry cleaners that are commonly found in community settings (*e.g.,* shopping centers and strip malls) are typically ''area sources,'' meaning they emit less than 10 tons of PCE each year and are smaller in size in comparison to major source industrial and commercial PCE dry cleaners. The PCE Dry Cleaning NESHAP standards for these area sources are GACT standards. The PCE Dry Cleaning NESHAP requires *existing* area source PCE dry cleaners operating dry-to-dry machines to:

- Use a halogenated hydrocarbon detector or PCE gas analyzer monthly to detect PCE leaks, repair the leaks, and maintain records.

New area source PCE dry cleaners operating dry-to-dry machines must:

- Operate non-vented dry-to-dry machines with a refrigerated condenser and secondary carbon adsorber.
- Use a halogenated hydrocarbon detector or PCE gas analyzer to detect PCE leaks, repair the leaks, and maintain records.

Petitions for judicial review of the 2006 amendments to the NESHAP were filed by the Sierra Club, Halogenated Solvents Industry, Neighborhood Cleaners Association, International Fabricare Institute, and Textile Care Allied Trades Association. *Sierra Club et al.* v. *USEPA,* No. 06–1330 (and consolidated cases) (D.C. Cir.). Petitioners questioned whether the EPA reasonably interpreted CAA section 112(d)(6) to allow consideration of risk and costs as factors in determining the extent to which it was necessary to revise standards regulating PCE; whether the EPA reasonably determined under section 112(d)(6) that it was necessary to revise standards regulating PCE, and to require elimination of PCE emissions at co-residential systems but not at other systems; whether the EPA had complied with the Regulatory Flexibility Act (RFA); and whether the EPA had reasonably denied a petition for reconsideration of the rule submitted by the Sierra Club. Although the case was fully briefed, in 2009 before it could be argued at the D.C. Circuit, the parties agreed to EPA taking a voluntary remand of the rule for the administration to consider whether further administrative action was warranted regarding the challenged issues, while leaving the rule in force. As discussed in section III.A of this preamble, we are finalizing our response to the voluntary remand as part of this final rule making.

C. What changes did we propose for the PCE Dry Cleaning NESHAP in our December 27, 2021, proposal?

On December 27, 2021, the EPA published a proposed rule in the **Federal Register** for the PCE Dry Cleaning NESHAP that took into consideration the TR analyses. We

[1] Estimated quantity of major source PCE dry cleaners is based on details provided to EPA by state regulators, State small business environmental assistance providers' programs (SBEAP) personnel, and industry trade association representatives. Refer to the docket for this rule (Docket ID No. EPA–HQ–OAR–2005–0155).

proposed to require that all PCE dry to dry machines at existing major and areas sources have both refrigerated condensers and carbon adsorbers as secondary controls. At the time this action was proposed, the available data indicated that no third-generation machines were still in use and since fourth and fifth generation machines already use both refrigerated condensers and carbon adsorbers, the proposed amendment would have no costs or economic impacts. We also proposed a response to the 2009 voluntary remand, stating that the 2006 RTR was appropriate and proposed no changes from how we addressed the PCE ban and phaseout for co-residential sources.

III. What is included in this final rule?

This action finalizes the EPA's determinations pursuant to the TR provisions of CAA section 112 for the PCE Dry Cleaning NESHAP.

A. What are the final rule amendments based on the technology review for the PCE Dry Cleaning NESHAP?

We are finalizing a determination that there are no necessary revisions to the NESHAP after considering developments in practices, processes, and control technologies. We note that, as discussed in section IV of this document, a separate regulatory action under TSCA has finalized a 10-year phaseout of the use of PCE in dry cleaning. Therefore, we are not finalizing revisions to the currently promulgated NESHAP standards under CAA section 112(d)(6). Further, in response to the voluntary remand of the 2006 RTR, we are likewise concluding that no further evaluation of the NESHAP's approach to addressing the PCE ban and phaseout for co-residential sources in the 2006 RTR is warranted, considering the EPA's recent more comprehensive prohibition of the use of PCE in dry cleaning and spot cleaning under TSCA.

IV. What is the rationale for our final decisions and amendments for the PCE Dry Cleaning source categories?

The EPA addressed the results of the TR for the PCE Dry Cleaning NESHAP in accordance with section 112(d)(6) of the Clean Air Act (CAA). This section provides a description of what we proposed and what we are finalizing, a summary of key comments and responses, and the EPA's rationale for the final decisions. For all comments not discussed in this preamble, comment summaries and the EPA's responses can be found in *Response to Comments National Perchloroethylene Air Emissions Standards for Dry Cleaning Facilities* available in the docket.

A. Technology Review for the PCE Dry Cleaning NESHAP

1. What did we propose pursuant to CAA section 112(d)(6) for the PCE Dry Cleaning NESHAP?

The proposed rule published on December 27, 2021 (86 FR 73207), proposed to require all sources subject to the PCE Dry Cleaning NESHAP, whether new or existing, to be equipped with refrigerated condensers and carbon adsorbers. The TR proposed that existing affected sources would comply with the proposed amendments in this rulemaking no later than 180 days after the effective date of the final rule. We estimated in the proposal that no third-generation machines were still in use, therefore, the proposed amendment would have no costs or other impacts.

We also proposed a response to the 2009 voluntary remand, stating that our approach in the 2006 RTR to base our decisions to revise the standards as necessary for dry cleaners located in residential settings, based in part on the unique public health impacts that the additionally mandated HAP reductions would mitigate in that context, was warranted under CAA section 112(d)(6).

2. How did the technology review change for the PCE Dry Cleaning NESHAP?

Upon further review and based on public comments, the EPA has determined that our understanding, outlined in our proposal, that all third-generation machines have been retired is not correct. However, since the PCE Dry Cleaning NESHAP proposal, in 2021 the EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) published an updated risk analysis on PCE under section 6(b) of the Toxic Substances Control Act (TSCA), finding unreasonable risk with PCE due to unreasonable carcinogenic risk, which triggered a duty for the EPA to promulgate a rule under section 6(a) of TSCA to address such unreasonable risk. In December 2024, OCSPP finalized a comprehensive rule addressing PCE that, among other things, prohibits the use of PCE in dry cleaning with a 10-year phaseout plan (hereafter referred to as the TSCA rule. See, Perchloroethylene (PCE); Regulation under the Toxics Substances Control Act (TSCA); Final Rule [to be codified at 40 CFR part 751, subpart G. As the EPA explained in the final TSCA rule, the TSCA rule phaseout of PCE use in dry cleaning starts with a prohibition on the industrial or commercial use of PCE in any dry cleaning machine acquired 180 days or later after publication of the final TSCA rule, followed by a prohibition on the industrial or commercial use of PCE in third generation machines three years after publication of the final rule. The final TSCA rule was published in the **Federal Register** on December 18, 2024 (89 FR 103560). Full implementation of the phaseout will be achieved 10 years after publication of the final TSCA rule with a prohibition on the use of PCE in all dry cleaning and spot cleaning, including in fourth and fifth generation machines, and a prohibition on the manufacturing, processing, and distribution in commerce of PCE for use in dry cleaning solvent.

As a result of the TSCA rule prohibiting use of PCE in dry cleaning with a 10-year phaseout plan, which the EPA explained was consistent with requirements in TSCA section 6(d)(1)(C) and (D) to specify mandatory compliance dates for the start of the phaseout requirements that are as soon as practicable but not later than five years after the final TSCA rule's promulgation and to specify mandatory compliance dates for full implementation of phaseout requirements that are as soon as practicable, as well as providing a reasonable transition period consistent with TSCA section 6(d)(1)(E), the EPA is finalizing no changes to the CAA NESHAP. Regarding the proposed retrofit of older third generation systems specifically, as the TSCA rule prohibits the use of such machines after three years from its promulgation and prohibits acquiring any new dry cleaning machines that use PCE 180 days after publication of the final TSCA rule, it is unnecessary to additionally require retrofitting of third generation machines separately under the PCE Dry Cleaning NESHAP. Requiring such retrofitting of third generation machines under the NESHAP could result in their becoming reconstructed new sources, and result in forcing owners and operators into risking violation of the TSCA rule's prohibition of acquiring new dry cleaning machines that use PCE.

3. What key comments did we receive on the technology review, and what are our responses?

Comment: One commenter believes that if the EPA had properly evaluated risk in the 2006 RTR, then the Agency would have phased out PCE completely in that rule, or at least in co-commercial facilities. They disagree with the EPA's position that the Agency is not obligated to perform risk assessments under CAA

section 112(f) on area sources. They highlighted ''uncontroverted record evidence showing that the risk from these facilities is 1,000-in-one million'' and that the proposed controls from the 2006 rule only reduced risk to 175-in-one million, which is above the 100-in-one million presumed acceptable benchmark used by the EPA is residual risk reviews.

The commenter claims ''no reasonable basis'' to not phase out PCE completely. They assert that alternative solvents can replace PCE without additional costs, that other States and municipalities have banned PCE, and that the EPA banned it for co-residential facilities. They believe that extant bans are a development in practices that should be considered under CAA section 112(d)(6). The commenter says the EPA did not explain why costs were unreasonable, nor why limitations of alternative solvents were significant enough to warrant needing PCE. They maintain that the Agency cannot argue that it does not have enough information to support a broader PCE ban since it did not attempt to solicit or collect such information, and the Agency has failed to ''grapple with record evidence undercutting its risk rationale for refusing to require a PCE phaseout at area source dry cleaners.''

A commenter claimed that in the Agency's response to comments for the 2006 rule, the EPA states that area sources do not warrant a ban on PCE. The commenter states that the Agency cannot use such a statutory interpretation because the EPA did not mention it in the proposed rule.

In addition, a commenter asked that the EPA consider the then-pending PCE TSCA risk evaluation recommendations and any potential new environmental regulations that may impact small business dry cleaning owner/operators.

Response: As noted in Section IV.A.2 of this document, the EPA's OCSPP has separately promulgated a final rule under section 6 of TSCA that prohibits the use of PCE in dry cleaning machines with a 10-year phaseout period for full compliance. The TSCA rule phaseout starts with a prohibition on use of PCE in any dry cleaning machine acquired 180 days or later after the publication of the final TSCA rule, followed by a prohibition on the use of PCE in third generation machines three years after publication. Consequently, the comments objecting to the 2006 rule's and the 2021 proposal's not more broadly prohibiting the use of PCE use at dry cleaners are now moot, and it is not necessary to further respond to them.

The EPA agrees that appropriate offices within the Agency should collaborate when addressing emission sources controlled under multiple regulations. Although the NESHAP and TSCA rules must meet different obligations and consider different factors, the EPA's OCSPP coordinated with the Office of Air & Radiation (OAR) in conducting the TSCA rulemaking. Likewise, the EPA's OAR has coordinated with OCSPP in this NESHAP action, to ensure the rules are consistent and are not unnecessarily duplicative, redundant, or in conflict.

Comment: Commenters expressed opposition to the EPA's proposed compliance deadline of no later than 180 days after the effective date of the final rule for existing affected sources.

Commenters assert that there are many facilities which still operate third generation machines past their typical lifespan. The industry is already suffering from lower demand due to COVID–19 making it harder to afford machine upgrades and/or replacement. Further, supply chain issues combined with lack of in-stock supplies and no domestic manufacturers make it unreasonably difficult to purchase appropriate machines or add-on controls in under six months.

One commenter recommended a compliance deadline of at least three years. They justify their position by pointing out that NESHAPs usually allow for up to three years to comply, and that the EPA's previous amendments to the PCE Dry Cleaning NESHAP allowed a 15-year phaseout of PCE machines from co-residential facilities. The Commenter recommended a three- to-five year compliance timeframe.

Response: The EPA acknowledges that our expectation in 2021 that there were no third generation machines in operation was incorrect. However, as noted in Section IV.A.2 of this document, the EPA's OCSPP has promulgated a rule under the TSCA that prohibits the use of PCE in dry cleaning machines with a 10-year phaseout period, beginning with a prohibition on the use of PCE in any machine acquired 180 days or later after the TSCA rule's publication and followed by a prohibition on the use of PCE in third generation machines three years after its publication. As a result, we are not additionally finalizing our proposed amendments to the NESHAP to require add-on controls for third generation machines, as the control requirements are no longer necessary.

4. What is the rationale for our final approach for the technology review?

In 2022, the EPA's OCSPP published a final revised risk determination on PCE under the TSCA, finding that PCE presents an unreasonable risk to human health under its conditions of use, including in dry cleaning. Under TSCA section 6(a), if the Agency determines through a TSCA section 6(b) risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, EPA must by rule apply one or more requirements listed in TSCA section 6(a) to the extent necessary so that the chemical substance or mixture no longer presents such risk. The unreasonable risk is largely driven by factors not traditionally considered in conducting risk reviews for NESHAP, such as onsite worker exposure and dermal exposures to non-air forms of the chemical. The technical and scientific record for the TSCA risk assessment was broader and more comprehensive than the EPA's proposed 2021 NESHAP amendments.

In June 2023, the EPA's OCSPP proposed a rule under TSCA (87 FR 39085, June 30, 2022) to ban the use of PCE in dry cleaning, subject to a phaseout of 6 months to 10 years for the various types of equipment (88 FR 39652, June 16, 2023). This rule was promulgated as a final rule and contains a ban on the use of PCE that takes effect in 180 days for newly acquired machines and up to 10 years for existing machines. The TSCA rule prohibits the use of PCE in industrial or commercial third generation machines three years after publication of the final rule.

As a result of the EPA's TSCA rule requiring a prohibition on the use of PCE in dry cleaning machines, the EPA has determined it is not necessary to finalize additional changes to the PCE Dry Cleaning NESHAP under the CAA section 112(d)(6) technology review for the PCE dry cleaning source categories.

V. Summary of Cost, Environmental, and Economic Impacts and Additional Analyses Conducted

A. What are the affected facilities?

The PCE Dry Cleaning NESHAP prescribes a combination of equipment, work practices, and operational requirements. The NESHAP defines major and area sources based on the annual PCE purchases for all machines at a facility. The consumption criterion (which affects the amount of PCE purchased) varies depending on multiple variables, including number of machines, size of business, etc. The affected source is each individual dry cleaning system that uses PCE.

Consequently, a single dry cleaning facility could be comprised of multiple affected sources if it has multiple dry cleaning systems onsite. As a result, some of a facility's systems could be subject to ''new'' source requirements under the NESHAP, and some could be ''existing'' sources, depending upon when they were placed into service. The TSCA rule estimated that 6,000 dry cleaners still use PCE.

B. What are the air quality, cost, economic impacts, and benefits?

As there are no changes to the NESHAP requirements resulting from the final TR, there are no expected air quality, cost, or economic impacts or benefits as a result of this rulemaking.

C. What analysis of environmental justice did we conduct?

Because we are not finalizing any changes to the NESHAP as a result of the EPA's TSCA rule prohibiting the use of PCE in dry cleaning machines, we did not conduct a new analysis of environmental justice for this action. For more information, the methodology and the results of the demographic analysis conducted for the proposed rule are presented in a technical report, *Analysis of Demographic Factors for Populations Living Near the Dry-Cleaning Major and Area Sources,* available in the docket for this action (Document ID EPA–HQ–OAR–2005–0155–0597).

D. What analysis of children's environmental health did we conduct?

Because we are not finalizing any changes to the NESHAP as a result of the EPA's TSCA rule prohibiting the use of PCE in dry cleaning machines, we did not conduct an analysis of children's environmental health in this action.

VI. Statutory and Executive Order Reviews

A. Executive Orders 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is not a significant regulatory action as defined in Executive Order 12866, as amended by Executive Order 14094, and was therefore not subject to a requirement for Executive Order 12866 review.

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden. No new information collection is required as part of this final action; owners and operators will continue to keep records and submit required reports to the EPA, or the delegated State regulatory authority required in the final rule. However, the Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations (40 CFR 63 subpart M) under the provisions of the Paperwork Reduction Act 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060–0234. The OMB control number for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action are industrial and commercial dry cleaning facilities that use PCE. The North American Industry Classification System (NAICS) codes applicable to 40 CFR part 63, subpart M, are 812310 (coin-operated laundries and dry cleaners), 812320 (dry cleaning and laundry services other than coin-operated services), and 812332 (industrial launderers). The small business size definitions for those industries are $8.0 million, $6.0 million, and $41.5 million respectively. We are not finalizing any new requirements under this action and, therefore, we do not anticipate any small entities to incur costs due to this action. We conclude that this action will not have a significant economic impact on a substantial number of small entities.

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 or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

As discussed in the proposed rule, this action has Tribal implications. However, it will neither impose substantial direct compliance costs on federally recognized Tribal governments, nor preempt Tribal law. The EPA consulted with Tribal officials under the EPA Policy on Consultation and Coordination with Indian Tribes early in the process of developing this regulation to permit them to have meaningful and timely input into its development.

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

Executive Order 13045 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 reasonably feasible alternatives. This action is not subject to Executive Order 13045 because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

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. This action does not impact energy supply, distribution, or use.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

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

The EPA believes that this action is not likely to result in new disproportionate and adverse effects on communities with environmental justice concerns. More information can be found in the technical report, *Analysis of Demographic Factors for Populations Living Near the Dry-Cleaning Major and Area Sources,* available in the docket for

this action (Document ID EPA–HQ–OAR–2005–0155–0597). Additionally, the EPA notes that, separately, the TSCA rule is imposing at 10-year phaseout of the use of PCE in dry cleaning. The EPA explained in the TSCA rule that it believes it will likely reduce existing disproportionate and adverse effect on communities with environmental justice concerns.

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 in 40 CFR Part 63

Environmental protection, Administrative practice and procedures, Air pollution control, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Michael S. Regan,

Administrator.

[FR Doc. 2024–31223 Filed 1–6–25; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 240304–0068; RTID 0648–XE600]

Fisheries of the Exclusive Economic Zone Off Alaska; Reallocation of Pacific Cod in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; reallocation.

SUMMARY: NMFS is reallocating the projected unused amount of Pacific cod total allowable catch (TAC) from vessels using jig gear, to catcher vessels less than 60 feet (18.3 meters (m)) length overall (LOA) using hook-and-line or pot gear in the Bering Sea and Aleutian Islands (BSAI) management area. This action is necessary to allow the A season apportionment of the 2025 total allowable catch of Pacific cod to be harvested.

DATES: Effective January 2, 2025, through 2,400 hours, Alaska local time (A.l.t.), December 31, 2025.

FOR FURTHER INFORMATION CONTACT: Andrew Olson, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (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 apportionment of the 2025 Pacific cod TAC specified for vessels using jig gear in the BSAI is 1,067 metric tons (mt) as established by the final 2024 and 2025 harvest specifications for groundfish in the BSAI (89 FR 17287, March 11, 2024) and inseason adjustment (89 FR 105478, December 27, 2024).

The 2025 Pacific cod TAC allocated to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear in the BSAI is 2,525 mt as established by final 2024 and 2025 harvest specifications for groundfish in the BSAI (89 FR 17287, March 11, 2024) and inseason adjustment (89 FR 105478, December 27, 2024).

The Administrator, Alaska Region, NMFS, (Regional Administrator) has determined that jig vessels will not be able to harvest 1,000 mt of the A season apportionment of the 2025 Pacific cod TAC allocated to those vessels under § 679.20(a)(7)(ii)(A)(*1*). Therefore, in accordance with § 679.20(a)(7)(iv)(C), NMFS apportions 1,000 mt of Pacific cod from the A season jig gear apportionment to the annual amount specified for catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear.

The harvest specifications for 2025 Pacific cod included in final 2024 and 2025 harvest specifications for groundfish in the BSAI (89 FR 17287, March 11, 2024) and inseason adjustment (89 FR 105478, December 27, 2024) are revised as follows: 67 mt to the A season apportionment and 779 mt to the annual amount for vessels using jig gear, and 3,525 mt to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear.

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 reallocation of Pacific cod specified from jig vessels to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of December 31, 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: January 2, 2025.

Karen H. Abrams,

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

[FR Doc. 2025–00112 Filed 1–2–25; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 90, No. 4
Tuesday, January 7, 2025

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–2499; Airspace Docket No. 24–ANM–116]

RIN 2120–AA66

Establishment of Class E Airspace; Blanding Municipal Airport, Blanding, UT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace extending upward from 700 feet above the surface and revoke Class E airspace extending from 1,200 feet above the surface at Blanding Municipal Airport, Blanding, UT. Additionally, this action proposes administrative amendments to update the airport's legal description. These actions would support the airport's current instrument flight rules (IFR) operations that lack containment.

DATES: Comments must be received on or before February 21, 2025.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2024–2499 and Airspace Docket No. 24–ANM–116 using any of the following methods:

* *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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

FOR FURTHER INFORMATION CONTACT: Nathan A. Chaffman, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–3460.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would establish Class E airspace extending upward from 700 feet above the surface to support IFR operations at Blanding Municipal Airport, Blanding, UT.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy*.

Availability of Rulemaking Documents

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Operations office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the office at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198.

Incorporation by Reference

Class E5 airspace designations are published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11J, dated July 31, 2024 and effective September 15, 2024. These updates would be published in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 that would establish Class E airspace extending upward from 700 feet above the surface and revoke Class E airspace extending upwards from 1,200 feet above the surface at Blanding Municipal Airport, Blanding, UT.

Class E airspace extending upward from 700 feet should be established within a 6.2-mile radius of the airport, excluding that airspace parallel to the runway 3.1 miles west. Additionally, the Class E airspace should extend to the northeast to contain departing IFR operations until they reach 1,200 feet above the surface.

Class E airspace extending upward from 1,200 feet above the surface should be revoked as it is made redundant by Denver Class E En Route Domestic Airspace.

Finally, the legal description's geographical coordinates should be updated to match the FAA's database.

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ANM UT E5 Blanding, UT [Amended]

Blanding Municipal Airport, UT
(Lat. 37°35′00″ N, long. 109°28′60″ W)

That airspace extending upward from 700 feet above the surface within a 6.2-mile radius of the airport, excluding that airspace parallel to the runway 3.1 miles west, within 2.1 miles northwest and 2.9 miles southeast of the airport's 032° bearing extending from the 6.2-mile radius to 11.9 miles northeast.

* * * * *

Issued in Des Moines, Washington, on December 30, 2024.

B.G. Chew,

Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2024–31693 Filed 1–6–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–2099; Airspace Docket No. 24–ANM–105]

RIN 2120–AA66

Modification of Class E Airspace; Battle Mountain Airport, Battle Mountain, NV

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify the Class E airspace area designated as surface area, establish a Class E airspace area designated as an extension to a Class D or Class E surface area, modify Class E airspace extending upward from 700 feet above the surface of the earth, and remove Class E airspace extending upward from 1,200 feet above the surface at Battle Mountain Airport, Battle Mountain, NV. Additionally, this action proposes administrative amendments to update the airport's existing Class E airspace legal descriptions. These actions would support the safety and management of instrument flight rules (IFR) operations at the airport.

DATES: ≤Comments must be received on or before February 21, 2025.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2024–2099 and Airspace Docket No. 24–ANM–105 using any of the following methods:

* *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200

New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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

FOR FURTHER INFORMATION CONTACT: Keith T. Adams, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–2428.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would establish new and modify existing Class E airspace to support IFR operations at Battle Mountain Airport, Battle Mountain, NV.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Availability of Rulemaking Documents

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Operations office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the office at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198.

Incorporation by Reference

Class E airspace designations are published in paragraphs 6002, 6004, and 6005, respectively, of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11J, dated July 31, 2024 and effective September 15, 2024. These updates would be published in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to modify the Class E airspace area designated as surface area, establish a Class E airspace area designated as an extension to a Class D or Class E surface area, modify Class E airspace extending upward from 700 feet above the surface of the earth, and remove Class E airspace extending upward from 1,200 feet above the surface at Battle Mountain Airport, Battle Mountain, NV.

The Class E airspace area designated as surface area should be expanded from a 4.2-mile radius to a 4.4-mile radius and have a .1-mile extension to the southwest of the airport to more appropriately contain departing IFR aircraft executing the Runway (RWY) 22 obstacle departure procedure while between the surface and the base of adjacent controlled airspace.

In addition, Class E airspace designated as an extension to a Class D or Class E surface area should be established southwest of the airport to contain arriving IFR aircraft on the Very High Frequency Omnidirectional Range (VOR) RWY 4 approach while descending below 1,000 feet above the surface.

Moreover, the Class E airspace extending upward from 700 feet above the surface should be expanded to a 5-mile radius through all but the northwest portion to better contain arriving IFR aircraft descending below 1,500 feet and departing IFR aircraft until reaching 1,200 feet above the surface. The northeast extension should be realigned to the 051° and lengthened to appropriately contain arriving IFR aircraft below 1,500 feet above the surface while executing the Area Navigation (RNAV) (Global Positioning System [GPS]) RWY 22 approach. The southwest extension should be reduced in size to appropriately contain arriving IFR aircraft descending through 1,500 feet above the surface while executing the VOR RWY 4 or RNAV (GPS) RWY 4 approaches, departing IFR aircraft while executing the RNAV (GPS) RWY 13 or RNAV (GPS) RWY 33 departure procedures, and IFR aircraft ascending via the RNAV (GPS) RWY 22 missed approach procedure until reaching 1,200 feet above the surface. The northwest portion of the radius should be reduced in size and have an extension 3.6 miles wide extending on the 319° bearing from the 5-mile radius to 6.7 miles northwest of the airport to more appropriately contain IFR aircraft departing RWY 31 while climbing from 700 feet the 1,200 feet above the surface.

Furthermore, the Battle Mountain Class E airspace beginning at 1,200 feet above the surface should be removed as it is redundant.

Finally, the FAA proposes administrative modifications to the airport's associated legal description. Reference to the Battle very high frequency omnidirectional range tactical air navigation (VORTAC) on line 3 of the existing Class E5 legal descriptions is no longer needed and should be removed. The airspace should be described using the airport reference point.

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

Paragraph 6002 Airspace Areas Designated as Surface Area.

* * * * *

ANM NV E2 Battle Mountain, NV [Amended]

Battle Mountain Airport, NV
(Lat. 40°35′57″ N, long. 116°52′28″ W)

That airspace extending upward from the surface within a 4.4-mile radius of the airport and within 1.8 miles southeast and 1.9 miles northwest of the 228° bearing extending from the 4.4-mile radius to 4.5 miles southwest of the airport.

* * * * *

Paragraph 6004 Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

ANM NV E4 Battle Mountain, NV [New]

Battle Mountain Airport, NV
(Lat. 40°35′57″ N, long. 116°52′28″ W)

That airspace extending upward from the surface within 2.9 miles southeast and 3.4 miles northwest of the 221° bearing extending from the 4.4-mile radius to 10.4 miles southwest of the airport excluding that airspace within the Battle Mountain Airport Class E2.

* * * * *

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

ANM NV E5 Battle Mountain, NV [Amended]

Battle Mountain Airport, NV
(Lat. 40°35′57″ N, long. 116°52′28″ W)

That airspace extending upward from 700 feet above the surface within a 5-mile radius of the airport, within 4.9 miles northwest and 1.9 miles southeast of the 051° bearing extending from the 5-mile radius to 11.1 miles northeast of the airport, within 3.5 miles southeast and 3.6 miles northwest of the 221° bearing extending from the 5-mile radius to 11.5 miles southwest of the airport, within 1.8 miles either side of the 319° bearing extending from the 5-mile radius to 6.7 miles northwest of the airport, and within a 5.5-mile radius clockwise from 40°41′1″ N, 116°55′12″ W to 40°41′19″ N, 116°53′58″ W.

* * * * *

Issued in Washington, DC, on December 30, 2024.

B.G. Chew,

Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2024–31694 Filed 1–6–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 106 and 117

[Docket No. FDA–2024–D–2604]

Establishing Sanitation Programs for Low-Moisture Ready-To-Eat Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a draft guidance for industry entitled ''Establishing Sanitation Programs for Low-Moisture Ready-to-Eat Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event.'' The draft guidance, when finalized, will explain FDA's current thinking on establishing a routine sanitation program for low-moisture ready-to-eat human foods (LMRTE foods) that can help prevent contamination of food or a food-contact surface with a pathogen and will explain our current thinking for corrective actions, including corrective actions to remediate contamination of food-contact surfaces, if prevention fails.

DATES: Submit either electronic or written comments on the draft guidance by May 7, 2025, to ensure that the Agency considers your comment on the draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such

as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–2604 for ''Establishing Sanitation Programs for Low-Moisture Ready-to-Eat Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Microbiological Food Safety, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Benjamin Warren, Office of Microbiological Food Safety, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–645–7004, *Benjamin.Warren@fda.hhs.gov;* or Linda S. Kahl, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2784, *Linda.Kahl@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Establishing Sanitation Programs for Low-Moisture Ready-to-Eat Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event.'' We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

We are issuing this draft guidance to help manufacturers/processors of LMRTE foods comply with 21 CFR part 117 and, for powdered infant formula, 21 CFR part 106. Examples of LMRTE foods are powdered infant formula, peanut butter, nut butters, powdered drink mixes, chocolate, medical foods in powdered and paste forms, processed tree nuts, milk powders, powdered spices, snack foods such as chips and crackers, granola bars, and dry cereal. When finalized, the recommendations in this guidance can help manufacturers/processors of LMRTE foods consider and take actions to help ensure a safe and sanitary food supply through current good manufacturing practices and to establish and implement hazard analysis and risk-based preventive controls for these foods. The draft guidance, when finalized, will explain our current thinking on establishing a routine sanitation program for LMRTE foods that can help prevent contamination of food or a food-contact surface with a pathogen and will explain our current thinking on recommendations for corrective actions, including corrective actions to remediate contamination of food-contact surfaces, if prevention fails.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 106 have been approved under OMB control number 0910–0256. The collections of information in 21 CFR part 117 have been approved under OMB control number 0910–0751.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/FoodGuidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31528 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R6–ES–2024–0115; FXES1113090FEDR–256–FF09E22000]

RIN 1018–BH97

Endangered and Threatened Wildlife and Plants; Removal of Ute Ladies'-Tresses From the List of Endangered and Threatened Plants

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to remove Ute ladies'-tresses (*Spiranthes diluvialis*) from the Federal List of Endangered and Threatened Plants. This determination also serves as our 12-month finding on a petition to delist Ute ladies'-tresses. After a review of the best available scientific and commercial information, we find that delisting the species is warranted. Our review indicates that the threats to Ute ladies'-tresses have been eliminated or reduced to the point that the species no longer meets the definition of an endangered or threatened species under the Endangered Species Act of 1973, as amended (Act). Accordingly, we propose to delist Ute ladies'-tresses. If we finalize this rule as proposed, the prohibitions and conservation measures provided by the Act, particularly through sections 7 and 9, would no longer apply to Ute ladies'-tresses. We request information and comments from the public regarding this proposed rule and the draft post-delisting monitoring (PDM) plan for Ute ladies'-tresses.

DATES: We will accept comments received or postmarked on or before March 10, 2025. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. eastern time on the closing date. We must receive requests for public hearings, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by February 21, 2025.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *https://www.regulations.gov.* In the Search box, enter FWS–R6–ES–2024–0115, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, check the Proposed Rule box to locate this document. You may submit a comment by clicking on ''Comment.''

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS–R6–ES–2024–0115, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *https://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

Availability of supporting materials: This proposed rule and supporting documents, including the 5-year review, draft recovery plan, draft post-delisting monitoring plan (PDM), and the species status assessment (SSA) report, are available at *https://www.regulations.gov* under Docket No. FWS–R6–ES–2024–0115 and on the Service's website at *https://ecos.fws.gov/ecp/species/2159.*

FOR FURTHER INFORMATION CONTACT: George Weekley, Field Office Supervisor, U.S. Fish and Wildlife Service, Utah Ecological Services Field Office, 2369 West Orton Circle, Suite 50, West Valley City, UT 84119; telephone 801–239–0561. 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. Please see Docket No. FWS–R6–ES–2024–0115 on *https://www.regulations.gov* for a document that summarizes this proposed rule.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, a species warrants delisting if it no longer meets the definition of an endangered species (in danger of extinction throughout all or a significant portion of its range) or a threatened species (likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range). Ute ladies'-tresses is listed as threatened, and we are proposing to delist it. We have determined Ute ladies'-tresses does not meet the Act's definition of an endangered or threatened species. Delisting a species can be completed only by issuing a rule through the Administrative Procedure Act rulemaking process (5 U.S.C. 551 *et seq.*).

What this document does. This action proposes to remove Ute ladies'-tresses from the List of Endangered and Threatened Plants (*i.e.,* ''delist'' the species) based on its recovery.

The basis for our action. Under the Act, we may determine that a species is an endangered species or a threatened species because of any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. The determination to delist a species must be based on an analysis of the same factors.

Under the Act, we must review the status of all listed species at least once every 5 years. We must delist a species if we determine, based on the best available scientific and commercial data, that the species is neither an endangered species nor a threatened species. Our regulations at 50 CFR 424.11(e) identify four reasons why we might determine a species shall be delisted: (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. We have determined that Ute ladies'-tresses has recovered to the point at which it no longer meets the definition of an endangered species or a threatened species; therefore, we are proposing to delist it.

Information Requested

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or

information from other concerned governmental agencies, Native American Tribes, the scientific community, industry, or any other interested parties concerning this proposed rule.

We particularly seek comments concerning:

(1) Reasons we should or should not remove Ute ladies'-tresses from the List of Endangered and Threatened Plants;

(2) Relevant data concerning any threats (or lack thereof) to Ute ladies'-tresses, particularly any data on the possible effects of climate change as it relates to habitat, as well as the extent of State protection and management that would be provided to this plant as a delisted species;

(3) Current or planned activities within the geographic range of Ute ladies'-tresses that may have either a negative or positive impact on the species; and

(4) Considerations for post-delisting monitoring, including monitoring protocols and length of time monitoring is needed, as well as triggers for reevaluation.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for, or opposition to, the action under consideration without providing supporting information, although noted, do not provide substantial information necessary to support a determination. Section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered species or a threatened species must be made solely on the basis of the best scientific and commercial data available.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via *https://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *https://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *https://www.regulations.gov.*

Our final determination may differ from this proposal because we will consider all comments we receive during the comment period as well as any information that may become available after this proposal. For example, based on the new information we receive (and if relevant, any comments on that new information), we may conclude that the species should remain listed as threatened, or we may conclude that the species should be reclassified from threatened to endangered. We will clearly explain our rationale and the basis for our final decision, including why we made changes, if any, that differ from this proposal.

Public Hearing

Section 4(b)(5) of the Act provides for a public hearing on this proposal, if requested. Requests must be received by the date specified in **DATES**. Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT**. We will schedule a public hearing on this proposal, if requested, and announce the date, time, and place of the hearing, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing. We may hold the public hearing in person or virtually via webinar. We will announce any public hearing on our website, in addition to the **Federal Register**. The use of these virtual public hearings is consistent with our regulation at 50 CFR 424.16(c)(3).

Peer Review

A species status assessment (SSA) team prepared an SSA report for Ute ladies'-tresses. The SSA team was composed of Service biologists, in consultation with other species experts from Federal agencies, State wildlife and heritage programs, and local conservation groups. The SSA report represents a compilation of the best scientific and commercial data available concerning the status of the species, including the impacts of past, present, and future factors (both negative and beneficial) affecting the species.

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing and recovery actions under the Act, we solicited independent scientific review of the information contained in the Ute ladies'-tresses SSA report. The Service sent the SSA report to seven independent peer reviewers and received three responses. Results of this structured peer review process can be found at *https://www.regulations.gov* at Docket No. FWS–R6–ES–2024–0115. In preparing this proposed rule, we incorporated the results of these reviews, as appropriate, into the final SSA report, which is the foundation for this proposed rule.

Summary of Peer Reviewer Comments

As discussed in Peer Review above, we received comments from three peer reviewers on the draft SSA report. We reviewed all comments we received from the peer reviewers for substantive issues and new information regarding the contents of the SSA report. As discussed above, because we conducted this peer review prior to this proposed rule, we have already incorporated all applicable peer review comments in version 1.1 of the SSA report, which is the foundation for this proposed rule.

The peer reviewers provided additional information, clarifications, and recommendations pertaining to our analysis of Ute ladies'-tresses' current and future condition. We either incorporated or clarified substantial comments in the SSA report or address them below. In addition to substantive comments on the SSA report, we received several comments requesting the inclusion of additional biological information about orchids, more detail on the methods used in the suitable habitat model, and suggestions for climate change models to consider. Those comments were incorporated in the SSA report where applicable and are not summarized here.

(1) Comment: One reviewer was concerned with how we scored the overall current resiliency of analytical units (AUs). The reviewer stated that our scoring does not necessarily identify truly high resiliency conditions but rather provides a relative evaluation of AU resiliency, noting that an overall high resiliency score can be achieved even if one metric, such as vegetative habitat, is in low condition.

Our response: We developed our current condition evaluation in coordination with species experts, and our scoring reflects the relative contribution of each metric (*e.g.,* hydrological condition, vegetative habitat) to overall AU resiliency as discussed below in *Current Condition.* Ute ladies'-tresses is adapted to disturbance and changing hydrological and habitat conditions, and AUs may maintain high resiliency even when some of the species' needs are not being optimally met at individual occurrences or portions of those occurrences.

Therefore, our scoring of overall AU resiliency is appropriate.

(2) Comment: One reviewer commented that the comparisons of AU resiliency using the suitable habitat and connectivity metrics is problematic because different modeling approaches were used to generate suitable habitat in each AU based on the opinions of different biologists across the species' range. Therefore, the suitable habitat models were much more conservative, and therefore limited, for some AUs compared to others, resulting in inconsistencies in how AUs were evaluated for resiliency. The reviewer recommended that we use a standardized, rangewide method for the suitable habitat model.

Our response: We initially considered using a draft suitable habitat model using consistent methods recommended by the reviewer; however, input from species experts indicated that this model and other draft models overpredicted, rather than reasonably predicted, suitable habitat across the species' range. The modeling approach used in the SSA reflects local conditions and the variation across the range based on occurrence data within each AU, which would not be reflected using a standardized, rangewide method as recommended by the reviewer. When developing the final suitable habitat model, we incorporated recommendations from Service biologists in every State within the species' range to evaluate whether model predictions were a good reflection of suitable habitat for their respective AUs. The final model we relied on for our evaluation of suitable habitat in the SSA report is a combination of AU-level hydrologic unit code (HUC) 6 models and expert opinion, and we consider that model to provide the best representation of potentially suitable habitat for Ute ladies'-tresses given the species' life-history traits, occurrence data, and variation across its range.

Previous Federal Actions

On September 27, 1985, we published a notice of review in the **Federal Register** (50 FR 39526) issuing a list of plant taxa being considered for listing as endangered or threatened. Ute ladies'-tresses was included on this list as a Category 2 species. Category 2 species were taxa for which information in possession of the Service indicated that proposing to list them as endangered or threatened species was possibly appropriate, but we lacked conclusive data on biological vulnerability and threats to support the immediate preparation of a proposed rule.

On February 21, 1990, we published a notice of review in the **Federal Register** (55 FR 6184) reclassifying Ute ladies'-tresses from a Category 2 species to a Category 1 species based on a review of information collected since 1985. Category 1 species were taxa for which we had on file enough substantial information on biological vulnerability and threat(s) to support proposed rules to list them as endangered or threatened species. However, a proposed rule to list Ute ladies'-tresses was not issued because the action was precluded at the time by other listing activity. In the 1990 notice of review, we used the common name ''plateau lady's tresses'' for *Spiranthes diluvialis.*

On November 13, 1990, we published in the **Federal Register** (55 FR 47347) a proposed rule to list Ute ladies'-tresses as a threatened species due to the primary threat of water development and urbanization in its riparian habitat. At that time, the species was known to be comprised of fewer than 3,000 plants in 7 populations. Our proposed rule used ''Ute ladies'-tresses'' as the common name for *Spiranthes diluvialis* in recognition of the fact that the species' known historical range was used largely by the Ute Indian Tribe. We determined that it would not be prudent to designate critical habitat because the publication of critical habitat descriptions and maps would make this orchid species more vulnerable to collection.

Three additional populations were identified in Utah and Nevada prior to the final listing rule, for a total of 10 known populations with an estimated population size of fewer than 6,000 plants. On January 17, 1992, we published in the **Federal Register** (57 FR 2048) a final rule to list Ute ladies'-tresses as a threatened species. The final rule included a determination that the designation of critical habitat for Ute ladies'-tresses was not prudent.

When we listed Ute ladies'-tresses as a threatened species (see 57 FR 2048, January 17, 1992), we identified habitat loss and modification due to water development and urbanization (Factor A) as the primary threat to the species. We considered collection (Factor B) to be a threat because it is an orchid species. Disease and predation (Factor C) were not considered threats. Regulatory mechanisms (Factor D) included a limited degree of protection for the species' wetland habitat under the Clean Water Act (33 U.S.C. 1251 *et seq.*), and international trade for all orchids is regulated by the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES; 27 U.S.T. 1087, March 3, 1973). Finally, we identified the species' small and scattered populations, variable demographic structure of populations, and a presumed slow reproductive rate (Factor E) as making the species more vulnerable to other threats and stressors.

In 1995, we completed a draft recovery plan for the species (Service 1995, entire). To date, this plan has not been finalized.

On May 10, 1996, we received a petition from the Central Utah Water Conservancy District (CUWCD) to delist Ute ladies'-tresses pursuant to the Act (Christiansen 1996, entire). A ''Special Status Species Update'' for Ute ladies'-tresses, dated April 1996, accompanied the petition as supporting information (CUWCD 1996, entire). In response to the petitioner's request to delist Ute ladies'-tresses, we sent a letter to the petitioner on June 10, 1996, explaining our inability to act upon the petition due to the low priority assigned to delisting petitions in our 1996 Listing Priority Guidance (61 FR 24722, May 16, 1996).

On October 12, 2004, we published in the **Federal Register** (69 FR 60605) a 90-day finding that the 1996 petition contained substantial information indicating that delisting Ute ladies'-tresses may be warranted. However, higher priority work continued to preclude our ability to take further action on this petition. This proposed rule constitutes our 12-month finding on the May 10, 1996, petition to delist Ute ladies'-tresses under the Act.

In 2023, we completed an SSA report to evaluate the species' rangewide status and inform a 5-year status review. On August 8, 2023, we completed a 5-year review that recommended delisting Ute ladies'-tresses due to recovery.

Background

Species Description and Habitat Information

A thorough review of the taxonomy, life history, and ecology of Ute ladies'-tresses is presented in the SSA report, version 1.1 (Service 2024, entire). Ute ladies'-tresses is an herbaceous (not woody), perennial plant in the orchid family (*Orchidaceae*) found in the western United States and Canada. It is a terrestrial orchid (grows in the ground) and inhabits naturally occurring and human-created wetland habitats. When it was first described as a species in 1984, Ute ladies'-tresses was known to occur only in Utah and Colorado (Sheviak 1984, entire). Today, the species is found in eight U.S. States (Colorado, Idaho, Montana, Nebraska, Nevada, Utah, Washington, and

Wyoming) and southern British Columbia, Canada (Service 2024, p. 4).

Ute ladies'-tresses is a naturally occurring allopolyploid species, meaning it has more than one pair of chromosomes derived from the hybridization of two genetically distinct species (Szalanski et al. 2001, pp. 178–179). Ute ladies'-tresses is fertile (produces fertile offspring) but is not cross-compatible with either of its parent species, hooded lady's tresses (*Spiranthes romanzoffiana*) and Great Plains lady's tresses (*S. magnicamporum*) (Szalanski et al. 2001, pp. 178–179; Fertig et al. 2005, pp. 7–8). The ranges of hooded lady's tresses and Great Plains lady's tresses do not currently overlap with each other, but may have overlapped during the Pleistocene, a geological epoch that ended approximately 11,700 years ago (Sheviak 1984, p. 9). The hooded lady's tresses is present within the range of Ute ladies'-tresses but generally occupies higher elevations than Ute ladies'-tresses (above 7,000 feet (ft) (2,133 meters (m))), so the two species are mostly spatially separate within their overlapping ranges. Where they co-occur in Idaho, hooded lady's tresses flowers earlier than Ute ladies'-tresses (Moseley 2000, pp. 1–2).

A genetic study of Ute ladies'-tresses identified an unusually high degree of genetic variability within samples from several occurrences in Colorado and Utah, which suggests the species may have evolved from two or more separate hybridization events between hooded lady's tresses and Great Plains lady's tresses (Arft and Ranker 1998, p. 119). However, little genetic differentiation was found between samples from various occurrences in Colorado, Idaho, Montana, Nebraska, Utah, and Wyoming, suggesting that there may be a high degree of gene flow between Ute ladies'-tresses in those areas. No genetic studies have been conducted on Ute ladies'-tresses in the Upper Columbia basin of Washington and British Columbia, which is highly disjunct without any known connectivity to other occupied basins, or in the Lower Colorado-Lake Mead basin of Nevada, which contains a single isolated occurrence.

Ute ladies'-tresses plants are approximately 4.7 to 23.6 inches (in) (12 to 60 centimeters (cm)) tall and grow from tuberous-thickened roots (enlarged fleshy roots that store starch and nutrients). Basal leaves are grass-like, up to 11 in (28 cm) long, and leaves become progressively smaller up the stem (Sheviak 1984, entire). Flowers are small (0.3 to 0.6 in (7.5–15 millimeters (mm) long)), white or ivory-colored, and arranged in a gradual spiral along the flowering stalks (inflorescences) that inspired the ladies'-tresses part of the common name (Service 2024, p. 30). One diagnostic feature that distinguishes Ute ladies'-tresses from hooded lady's tresses is how fused the sepals (lower part of the flower that supports the petals) are to each other; the sepals of Ute ladies'-tresses are separate or fused only at the base, whereas the sepals of hooded lady's tresses are fused into a hood-like structure. Fruits are cylindric capsules with numerous seeds (Sheviak 1984, entire; Fertig et al. 2005, p. 7).

Ute ladies'-tresses has five life stages: seeds, seedlings, dormant plants, vegetative plants, and reproductive plants (Fertig 2020, p. 67; Service 2024, p. 31). Plants are perennial, appear to be long-lived, and likely depend on a specific symbiotic mycorrhizal (fungal) association during all life stages based on studies of other terrestrial orchids (Batty et al. 2002, pp. 196–197). Many terrestrial orchids have lifespans of 20 to 30 years or more, with at least one *Spiranthes* species having a lifespan of more than 60 years (Willems and Dorland 2010, p. 346; Shefferson et al. 2020, pp. 318–319).

Ute ladies'-tresses can likely reproduce asexually through root splitting (Fertig et al. 2005, p. 67), but the species primarily reproduces sexually through seed production. Plants cannot produce seeds without pollinators. The primary pollinators of Ute ladies'-tresses are bumblebees (*Bombus* spp.), solitary bees of the *Anthophora* genus, and honeybees (*Apis mellifera*) (Sipes and Tepedino 1995, entire; Sipes et al. 1995, pp. 1–3, 15–17; Pierson and Tepedino 2000, pp. 8, 16, 27–28). Plants typically flower in August and September (Fertig et al. 2005, p. 54), but the timing varies by location and local environmental conditions. Flowering has been documented as early as the beginning of July in Nevada, a hotter and drier part of the range, and as late as October in cooler, higher elevation occurrences (Great Basin Institute (GBI) 2009, p. 3; Ute ladies'-tresses Technical Team (ULT Tech) 2021, entire).

Orchid seeds are extremely small (the size of dust particles), are easily dispersed by wind and water, and do not provide much nourishment for the embryo (undeveloped plant) after germination (Sipes et al. 1995, p. 23). If the embryo can quickly form a mycorrhizal association, it is able to obtain nutrients directly from the soil fungi without relying on photosynthesis (Hildebrand 1998, p. 4; McGonigle and Sheridan 2004, p. 11; Yeung 2017, pp. 8–9). Seedlings persist underground and rely on the mycorrhizal association to develop shoots and leaves. It is unknown how long seedlings remain underground before transitioning to other life stages (vegetative or adult plants). We assume that Ute ladies'-tresses persist as a seedling for at least 1 year.

Ute ladies'-tresses may transition from being vegetative to reproductive or from reproductive to vegetative in subsequent aboveground years, and periods of dormancy below ground may occur throughout a plant's life (Yeung 2017, entire; ULT Tech 2021, entire; Service 2024, pp. 31–32). Plants can survive unfavorable conditions in a state of dormancy for multiple years (11 consecutive years or longer), either as a germinated seedling in a symbiotic mycorrhizal (fungal) association, known as a protocorm, or as an adult root mass (Fertig et al. 2005, p. 61). Adult plants do not emerge above ground or flower every year; flowering likely depends on environmental conditions and when the plant last flowered—a plant that flowered in the previous year may be more likely to remain vegetative or become dormant the following year (Willems and Dorland 2010, p. 345). It is difficult to track these cycles because humans can only reliably detect flowering plants, not other life stages (seeds, seedlings, dormant or vegetative plants), in the field (ULT Tech 2021, entire).

Ute ladies'-tresses has a ruderal (early colonizer of disturbed habitats) life-history strategy in which it can disperse within watersheds and quickly establish and produce seeds in favorable habitat conditions that may only be available for short periods of time (Gadgil and Solbrig 1972, entire). Ruderal plants are also able to persist in place and wait for favorable habitat conditions to return following disturbance events. The species disperses along connected waterways (river corridors, perennial streams, canals, lakeshores, wet meadows, and agricultural ditches), and plants appear in newly created or disturbed features (such as islands, point bars, shorelines) within the watershed. The species also persists in unsuitable habitat conditions that were previously suitable. Dormant Ute ladies'-tresses plants or seedlings can survive in late-seral successional habitats or unsuitable habitats below ground for years and then emerge above ground after disturbance reestablishes early- to mid-seral successional habitat conditions or adequate moisture is restored (Heidel 2001, entire). As mentioned above, we can only reliably detect flowering plants, and the species

does not necessarily flower every year. Therefore, Ute ladies'-tresses may appear to be extirpated from an area when in fact dormant or non-reproductive individuals are still present.

Range, Distribution, Abundance, and Trends of Ute Ladies'-Tresses

The current range of Ute ladies'-tresses spans eight States in the western United States (Colorado, Idaho, Montana, Nebraska, Nevada, Utah, Washington, and Wyoming) and the Canadian province of British Columbia (Service 2024, pp. 39–40). There are 62 extant Ute ladies'-tresses element occurrences (occurrences) distributed across 18 watershed basins, referred to as analytical units (AUs) and defined as populations in the SSA report. An AU may contain one or more element occurrences. The current range is much larger than the three States (Colorado, Nevada, and Utah) known to be occupied at the time of listing in 1992. Ute ladies'-tresses has not been found in Arizona, even though that State is considered to be part of two AUs (Lower Colorado-Lake Mead and Upper Colorado-Dirty Devil), because the species occurs in other States within those watersheds. Across its wide range, Ute ladies'-tresses is found in 3 different ecological classifications (Great Plains, North American Deserts, and Western Forested Mountains), 12 level-III ecoregions, and 7 habitat types (Fertig et al. 2005, pp. 21–33; U.S. Environmental Protection Agency 2013, entire; Service 2024, pp. 123–125).

At the time of listing in 1992, we reported 10 extant occurrences (defined as populations in the listing rule) with fewer than 6,000 plants and occurring on approximately 170 acres (ac) (69 hectares (ha)) of habitat (see 57 FR 2048, January 17, 1992). By 2005, there were known to be 52 extant occurrences with at least 83,316 flowering plants on 674 to 783 ac (273 to 317 ha) of habitat (Fertig et al. 2005, pp. 34–62). The 2005 flowering plant estimate was based on the maximum number of flowering plants reported over a multi-year period for each occurrence, since most surveys underestimate the number of dormant, vegetative, and fruiting plants in an occurrence (Fertig et al. 2005, p. 62). The current number of known extant occurrences has increased to 62. The number of flowering plants detected has likely also increased, but we do not provide an estimate of flowering plants in the SSA report for the following reasons: (1) there is a lack of consistent monitoring methods; (2) monitoring does not account for the geographic shifts in occupied habitat; and (3) monitoring does not account for four of the five life stages (seeds, seedlings, dormant plants, and vegetative plants) (ULT Tech 2021, entire). When a plant population contains dormant individuals, population size and trend can be accurately determined if we know the average number of years a plant is dormant and we can account for at least three life stages (dormant, vegetative, and flowering plants) (Lesica and Steele 1994, entire; Heidel 2001, p. 8; Fertig et al. 2005, pp. 61–62). However, this information is not available for Ute ladies'-tresses.

Ute ladies'-tresses occurrences demonstrate metapopulation structure within watersheds (AUs) where persistence is governed by the processes of patch colonization, extirpation (local extinction), and recolonization (Sipes et al. 1995, p. 26; Freckleton and Watkinson 2002, p. 419). These metapopulations are important to the viability of the species, as long-term persistence is generally higher in metapopulations than in small, isolated occurrences (Lesica 1992, p. 420). Consequently, identification of metapopulations and the availability of potentially suitable habitat is important for assessing the status of Ute ladies'-tresses (Freckleton and Watkinson 2002, p. 432; Service 2024, pp. 89–91).

In the SSA report, we delineated occurrences based on NatureServe criteria for water and land dispersal distances, which are grouped by plant locations connected by suitable habitat and generally less than 6.2 miles (mi) (10 kilometers (km)) and 1.2 mi (2 km) from each other along waterways and over land, respectively (NatureServe 2020, p. 6; Service 2024, p. 26). We know of 75 Ute ladies'-tresses occurrences, and we consider 62 of those occurrences to be currently occupied. We considered the 62 currently occupied occurrences in our analysis of current conditions if suitable habitat was still present, even if we had some negative observation data for a location. This assumption is consistent with field observations, expert opinion, and long-term monitoring data of occurrences in Nevada, Washington, and Utah (ULT Tech 2021, entire; Service 2024, pp. 31–32). In the SSA report, we also considered 13 historical occurrences, one of which was the only known occurrence in its AU (Upper Arkansas), to be extirpated based on the loss of occupied or suitable habitat due to development, change in hydrology, or imprecise historical records (Service 2024, pp. 100–110). We considered 11 of these historical occurrences, located in or near densely populated areas of Utah, Colorado, and Montana, to be extirpated because of urban development. Despite these losses, the current distribution of the species appears to be stable.

We refer to the watershed basins as AUs in the SSA report and consider them to be a surrogate for populations to better account for the species' widespread, dynamic distribution and complex life history. Given the detectability and monitoring limitations mentioned above, we consider the metapopulation structure—the number of occupied occurrences within a watershed (AU)—to be a better measure of population size rather than abundance counts of flowering plants. Considerably more occurrences have been discovered since listing in 1992, and new occurrences have been located every year for at least the past 10 years within known AUs. The most recent occurrence was discovered in 2023, after the species' 5-year status review was finalized, and in 2020, one occurrence was discovered in an AU previously considered extirpated (Atkin 2020, pers. comm.; Billings and Wheeler 2021, entire; Heidel 2023, entire; Service 2024, p. 77). However, this does not necessarily indicate an increasing population size or positive population trend for the species; it could be the result of an increased survey effort and awareness. Based on our measure of population size (*i.e.,* the number of occupied occurrences within an AU), the population trend for the species appears to be stable.

Our evaluation of population trend is based on our assessment of the availability of potentially suitable habitat within AUs. The suitable habitat model provides a relative estimate of the species' potential abundance within an AU to evaluate whether a watershed would continue to support metapopulation dynamics and the species' population needs (see *Current Condition,* below for more information).

Roughly 95 percent of the species' range occurs in the United States, with the remaining 5 percent of its range occurring in the province of British Columbia, Canada. In the United States, approximately 37 percent of land where the species occurs is federally owned or managed by the Bureau of Land Management (BLM), the U.S. Bureau of Reclamation (USBR), the U.S. Forest Service (USFS), the Service, the National Park Service (NPS), and the Department of Defense (DOD). Almost half of the land, approximately 47 percent, is under private ownership. There is a small amount (approximately 3 percent) of Ute ladies'-tresses habitat where the land ownership is not known. The remaining 13 percent of the species'

range is on State and Tribal lands (Service 2024, p. 39).

Recovery Criteria

Section 4(f) of the Act directs us to develop and implement recovery plans for the conservation and survival of endangered and threatened species unless we determine that such a plan will not promote the conservation of the species. Under section 4(f)(1)(B)(ii), recovery plans must, to the maximum extent practicable, include objective, measurable criteria which, when met, would result in a determination, in accordance with the provisions of section 4 of the Act, that the species be removed from the Lists of Endangered and Threatened Wildlife and Plants.

Recovery plans provide a roadmap for us and our partners on methods of enhancing conservation and minimizing threats to listed species, as well as measurable criteria against which to evaluate progress towards recovery and assess the species' likely future condition. However, they are not regulatory documents and do not substitute for the determinations and promulgation of regulations required under section 4(a)(1) of the Act. A decision to revise the status of a species or to delist a species is ultimately based on an analysis of the best scientific and commercial data available to determine whether a species is no longer an endangered species or a threatened species, regardless of whether that information differs from the recovery plan.

There are many paths to accomplishing recovery of a species, and recovery may be achieved without all of the criteria in a recovery plan being fully met. For example, one or more criteria may be exceeded while other criteria may not yet be accomplished. In that instance, we may determine that the threats are minimized sufficiently and that the species is robust enough that it no longer meets the definition of an endangered species or a threatened species. In other cases, we may discover new recovery opportunities after having finalized the recovery plan. Parties seeking to conserve the species may use these opportunities instead of methods identified in the recovery plan. Likewise, we may learn new information about the species after we finalize the recovery plan. The new information may change the extent to which existing criteria are appropriate for identifying recovery of the species. The recovery of a species is a dynamic process requiring adaptive management that may, or may not, follow all of the guidance provided in a recovery plan.

Here, we provide a summary of progress made toward achieving the draft recovery criteria for Ute ladies'-tresses. More detailed information related to conservation efforts can be found below under Summary of Biological Status and Threats. We completed a draft recovery plan for Ute ladies'-tresses in 1995 that has not been finalized (Service 1995, entire); however, the draft plan is nearly 3 decades old and no longer reflects the best scientific information available for Ute ladies'-tresses.

The draft plan describes a process for watershed-level planning and management to maintain and restore watershed conditions (*i.e.,* natural flows and hydrography, stream gradients, and soils) for the long-term persistence of the species (Service 1995, p. 15). The draft plan attempts to interpret and define ''ecosystem management'' and apply it to the recovery of Ute ladies'-tresses. The draft plan also states the expectation that population levels (occurrences in this case) and the amount of suitable habitat will fluctuate over time within a watershed (Service 1995, p. 15).

The draft plan states that specific population metrics were not identified because population viability is determined by habitat conditions and the maintenance of natural watershed processes. Therefore, the significance of population size and distribution can only be assessed in the ability of the watershed to support the species, and those linkages between watershed processes, habitat conditions, and population response are complex and not completely understood (Service 1995, p. 15).

Below, we identify the two delisting criteria described in the 1995 Ute ladies'-tresses draft recovery plan (Service 1995, p. 15), and the progress made to date in achieving the criteria. However, we acknowledge that because of advances in our understanding of Ute ladies'-tresses, the delisting criteria are not measurable, no longer reflect the best available science about the species, and may no longer be relevant.

Criteria for Delisting

Recovery Criterion 1: Viable populations throughout Ute ladies'-tresses' historical range and representative of its genetic endowment are maintained in riparian habitats of streams in a state of dynamic equilibrium.

Progress: We have a much better understanding of Ute ladies'-tresses current range since the time of listing in 1992. The known current range of Ute ladies'-tresses has expanded from three U.S. States (Utah, Colorado, and Nevada) to eight U.S. States (Colorado, Idaho, Montana, Nebraska, Nevada, Utah, Washington, and Wyoming) and the Canadian province of British Columbia (Service 2024, pp. 39–40). Based on information through 2023, there are a total of 62 extant occurrences of Ute ladies'-tresses distributed across 18 watershed basins (AUs defined as populations in the SSA report). The species' current range includes 14 more AUs than known at the time of listing when we apply the AU-scale to the known populations in 1992. We consider AUs to be synonymous with the criterion's use of ''populations,'' and the criterion does not specify the number of AUs needed to achieve recovery.

We note that the criterion references Ute ladies'-tresses' historical range. However, it is more appropriate to define recovery based on Ute ladies'-tresses' current range, because endangered and threatened species and their recovery are defined and evaluated based on their current range under the Act (see the definitions of ''endangered species'' and ''threatened species'' at 16 U.S.C. 1532(6) and (20), respectively). There is much uncertainty about Ute ladies'-tresses' historical range, and we may never know its true extent. Regarding the species' genetic endowment, preliminary genetic information indicates high genetic diversity in Ute ladies'-tresses occurrences assessed in six of the eight U.S. States within the current range (see Summary of Biological Status and Threats, below). We now consider morphological and ecological diversity in addition to genetic diversity in our evaluation of representation. While Ute ladies'-tresses does not exhibit morphological diversity, it has a high level of ecological diversity across its wide range, occupying 12 ecoregions and 7 habitat types (Service 2024, pp. 123–127).

Given what we now know about Ute ladies'-tresses ecological diversity, we consider all habitat types important for recovery, not just the riparian and stream habitats mentioned in the criterion. Therefore, we evaluated the viability of AUs in our SSA report for those AUs in riparian and perennial stream habitats as well as in the five other habitat types where it occurs (canals, wet meadows, springs, lakeshores, and artificial/depressional wetlands) (for more information, see *Current Condition* and *Future Scenarios and Future Condition,* below).

Recovery Criterion 2: Wet meadow, seep, and spring habitats are protected

and managed so as to sustain viable populations.

Progress: At the time of the draft recovery plan (1995), we thought that it was important to distinguish Ute ladies'-tresses' wet meadow, seep, and spring habitats that are groundwater-fed from other types of habitats. These habitat types require land management practices such as grazing or mowing to provide the regular disturbance needed to support the species, whereas the riparian and stream habitats referenced in criterion 1 are surface water-fed and receive regular or periodic flooding disturbance. In the SSA report, we consider seeps and springs together and refer to them as spring habitats (Service 2024, p. 125). These habitats can be isolated from other water features or occur in combination with riparian, stream, or lakeshore habitats. We have better information now about Ute ladies'-tresses' current range and the habitat types the species occupies than we did at the time of the draft recovery plan.

Given what we know about Ute ladies'-tresses' resiliency, redundancy, and representation, we no longer consider it necessary to provide a separate criterion for wet meadow, seep, and spring habitats. As we state above for criterion one, we consider all habitat types in the SSA report and in our evaluation of Ute ladies'-tresses' viability (for more information, see *Current Condition* and *Future Scenarios* and *Future Condition,* below).

The majority (roughly 95 percent) of Ute ladies'-tresses' current range occurs in the United States, with the remaining 5 percent of its range occurring in British Columbia, Canada. In the United States, approximately 37 percent of the land where the species occurs is federally owned or managed (by the BLM, USBR, USFS, the Service, NPS, or DOD) with management plans in place to protect the species' habitat from habitat loss associated with urban development. For Ute ladies'-tresses and its habitat, Federal land management adequately supports the needs and viability of the species, and we expect that will continue in the future (see *Conservation Efforts and Regulatory Mechanisms,* below).

Approximately 60 percent of the land where Ute ladies'-tresses occurs in the United States is under non-Federal ownership (private, State, or Tribal lands). Some occurrences in three AUs (Jordan, Bear River, and South Platte) have management plans in place to protect the species and its habitat on non-Federal lands. However, little to no protection exists for Ute ladies'-tresses on the remaining non-Federal lands other than habitat protections afforded by the Clean Water Act for occurrences along riparian, stream, and some lakeshore habitats, or habitat protections afforded to federally listed fish species (see *Conservation Efforts and Regulatory Mechanisms,* below).

Despite the lack of protections on many non-Federal lands for Ute ladies'-tresses, current and projected future AU-level threats are adequately addressed or managed on these lands for at least 10 AUs to maintain high or moderate resilience to stochastic events now and into the future. In addition, at least 16 AUs are projected to remain extant and provide additional redundancy and representation in the 12 ecoregions and 7 habitat types across Ute ladies'-tresses' range (see *Future Scenarios and Future Condition,* below). Thus, although not all 18 extant AUs are considered protected, we conclude that the intent of recovery criteria 1 and 2 to ensure that sufficient AUs are protected from threats into the future has been met for at least 10 AUs. While the 1995 recovery criteria are not measurable, and do not reflect the best available scientific information, as we describe below, we find that the Ute ladies'-tresses has sufficient resiliency, redundancy, and representation given what we now know about the species.

Regulatory and Analytical Framework

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations in title 50 of the Code of Federal Regulations set forth the procedures for determining whether a species is an endangered species or a threatened species, issuing protective regulations for threatened species, and designating critical habitat for endangered and threatened species.

The Act defines an ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range, and a ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether any species is an endangered species or a threatened species because of any of the following factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

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

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

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

The Act does not define the term ''foreseeable future,'' which appears in the statutory definition of ''threatened species.'' Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis which is further described in 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*). The foreseeable future extends as far into the future as the U.S. Fish and Wildlife Service and National Marine Fisheries Service (hereafter, the Services) can make reasonably reliable predictions about the threats to the species and the species' responses to those threats. We need not identify the foreseeable future in terms of a specific period of time. We 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. In other words, the foreseeable future is the period of time over which we can make reasonably reliable predictions. ''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.

Analytical Framework

The SSA report documents the results of our comprehensive biological review of the best scientific and commercial data regarding the status of the species, including an assessment of the potential threats to the species. The SSA report does not represent our decision on whether the species should be proposed for delisting. However, it does provide the scientific basis that informs our regulatory decisions, which involve the further application of standards within the Act and its implementing regulations and policies.

To assess the viability of Ute ladies'-tresses, we used the three conservation biology principles of resiliency, redundancy, and representation (Shaffer and Stein 2000, pp. 306–310). Briefly, resiliency is the ability of the species to withstand environmental and demographic stochasticity (for example, wet or dry, warm or cold years); redundancy is the ability of the species to withstand catastrophic events (for example, droughts, large pollution events), and representation is the ability of the species to adapt to both near-term and long-term changes in its physical and biological environment (for example, climate conditions, pathogen). In general, species viability will increase with increases in resiliency, redundancy, and representation (Smith et al. 2018, p. 306). Using these principles, we identified the species' ecological requirements for survival and reproduction at the individual, population, and species levels, and described the beneficial and risk factors influencing the species' viability.

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

The following is a summary of the key results and conclusions from the SSA report; the full SSA report can be found at Docket No. FWS–R6–ES–2024–0115 on *https://www.regulations.gov.*

Summary of Biological Status and Threats

In this discussion, we review the biological condition of the species and its resources, and the threats that influence the species' current and future condition, in order to assess the species' overall viability and the risks to that viability. In addition, the SSA report (Service 2024, entire) documents our comprehensive biological status review for the species, including an assessment of the potential threats to the species.

The following is a summary of this status review and the best available information gathered since that time that have informed this decision.

Individual Needs

Individuals of Ute ladies'-tresses need adequate soil moisture during the growing season, access to full or partial sunlight, and suitable soil mycorrhizae to establish, grow, and flower (Service 2024, pp. 31–34). While we do not know the species' surface or subsurface moisture requirements, soil moisture is generally provided by surface or subsurface water within 2 ft (0.6 m) of the ground surface (ULT Tech 2021, entire). An open canopy (little to no shade from plants above) is needed to provide full or partial sunlight to plants (Fertig et al. 2005, p. 34).

While we do not know the specific mycorrhizal fungi needed by Ute ladies'-tresses, their presence in the habitat is likely a limiting factor for the establishment and reproduction of Ute ladies'-tresses (Fertig et al. 2005, p. 67; ULT Tech 2021, entire). Bumblebees and other appropriate pollinators are needed for seed production (Sipes and Tepedino 1995, entire).

Individuals need certain habitat factors, including: a low- to mid-elevation climate (elevations ranging between 0 to 7,000 ft (0 to 2,133 m); early- to mid-seral stage successional wetland habitats; and some kind of periodic disturbance (flooding or scouring events, livestock grazing, agricultural mowing, fire, etc.) to maintain the habitat's seral stage (see Background, above).

Population Needs

To be resilient, populations require recruitment, survivorship, and reproduction at rates able to sustain populations, in addition to pollinator connectivity between individuals within populations. We consider the significant determinants of population (AU) resiliency to be a healthy demography and sufficient quality habitat to support this demography (Service 2024, pp. 93–96). Resilient populations also contain enough individuals in multiple habitat areas to bounce back after experiencing environmental stressors such as drought, livestock grazing, habitat disturbance, and demographic stochasticity (births, deaths, and reproductive events that fluctuate over time). While we do not know the number of individuals or amount of habitat needed for Ute ladies'-tresses populations to be resilient, we assume that Ute ladies'-tresses populations are most resilient if they contain multiple occurrences connected by potentially suitable habitat and if they occur within habitats that maintain adequate hydrology and the appropriate seral successional stage (Service 2024, pp. 95–98).

Species Needs

The number of populations (AUs) across the landscape influences the redundancy of Ute ladies'-tresses. More populations across the range increase the species' ability to withstand catastrophic events. Individuals and populations inhabiting diverse ecological settings and exhibiting genetic or phenological variation add to the level of representation across the species' range. The greater diversity observed in Ute ladies'-tresses' habitats, genetics, and morphology, the more likely the species is to be able to adapt to change over time. Ute ladies'-tresses exhibits a high level of ecological diversity, occupying 12 ecoregions and 7 habitat types (Service 2024, pp. 123–125). Additionally, the species showed

high genetic variability within some occurrences and low variability between occurrences, which suggests a high level of genetic exchange between populations historically and possibly currently (Arft and Ranker 1998, p. 119; Service 2024, p. 91).

In summary, the species needs (1) a sufficient number and distribution of resilient populations to withstand catastrophic events (redundancy) and (2) a range of variation that allows the species to adapt to changing environmental conditions (representation) (Service 2024, pp. 88–89). The SSA report provides additional detail on the species' individual-, population-, and species-level needs (Service 2024, pp. 29–38, 86–89).

Threats (Stressors/Risk Factors/Etc.)

In the SSA report, we evaluated stressors and other actions that can positively or negatively affect Ute ladies'-tresses at the individual, population, or species levels, either currently or into the future (Service 2024, pp. 89–95, 128–137). In this proposed rule, we will discuss only those factors in detail that could meaningfully impact the status of the species. The main stressors are anthropogenic activities (urban development, water management, agriculture, livestock grazing, recreation, and invasive plants) and environmental conditions (vegetative succession, drought, and climate change) that influence or could influence the species' viability (Service 2024, pp. 89–95, 128–137). We grouped the various anthropogenic activities together and the environmental conditions together to consider their synergistic and cumulative effect on Ute ladies'-tresses at the population and species levels, because none of the individual stressors alone act intensely or broadly enough to alter Ute ladies'-tresses' status across its range (ULT Tech 2021, entire). Those stressors that are not known to have negative or long-term effects on Ute ladies'-tresses populations, such as loss of pollinators and flooding, are not discussed here but are evaluated in the SSA report (Service 2024, p. 95).

Urban Development

Urban development has the potential to result in plant mortality and loss or degradation of Ute ladies'-tresses habitat (Service 2024, p. 90). We assessed the urban development stressor to Ute ladies'-tresses based on our evaluation of disturbance, as well as roads and other infrastructure, in and near known populations. Urban development has resulted in the loss of eight occurrences in or near densely populated areas—in Utah, six occurrences were lost in the Jordan and Weber AUs along the Wasatch Front, and in Colorado, two occurrences were lost in the South Platte and Upper Arkansas AUs along the Front Range, resulting in the extirpation of the Upper Arkansas AU (Service 2024, pp. 100–109). One occurrence in Utah (in the Upper Colorado-Dirty Devil AU) is likely extirpated due to change in the hydrology and habitat loss because of road construction (Fertig et al. 2005, p. 54; Service 2024, p. 67). Two occurrences in Montana (in the Upper Missouri AU) occur in borrow pits created to support road construction projects; however, Montana Department of Transportation has prioritized their protection and long-term monitoring (Service 2024, p. 73).

We incorporated this stressor in our evaluation of current resiliency by assessing the land use, habitat condition, and hydrological condition of occurrences (Service 2024, pp. 96–135). We incorporated this stressor in our evaluation of future resiliency by evaluating projected changes in land use and the human population (Service 2024, pp. 129–196).

Water Management

Water management has the potential to result in hydrologic changes that impact the amount of suitable habitat, soil moisture, and the successional stage of Ute ladies'-tresses habitat (Service 2024, p. 91). Water flow is managed for irrigation and flood control along many of the river corridors occupied by Ute ladies'-tresses, which may lead to additional suitable habitat in some areas and the loss of suitable habitat in other areas (Grams et al. 2002, entire; Fertig et al. 2005, p. 82, Service 2024, pp. 129–136). Water management has the potential to benefit Ute ladies'-tresses by maintaining flows in low water years, but negative impacts may occur if water releases are unpredictable and not consistent with the natural hydrologic regime. We discuss the effects of flood control, in particular the reduction of large flood events, on the successional stage of Ute ladies'-tresses habitat below (see ''Vegetative Succession,'' below).

Despite management of hydrology for purposes other than Ute ladies'-tresses conservation, the species has proliferated in areas with greatly altered wetland, riparian, and lakeshore habitats that occasionally experience 10,000-year flood events (*e.g.,* Diamond Fork occurrence (Jordan AU), Lower Green River AU) (Central Utah Water Conservation District (CUWCD) 1996, pp. 4–3–4–9, 4–11–4–12; Central Utah Project Completion Act Office (CUPCA) 1999, entire; Ward and Naumann 1998, entire; Grams et al. 2002, entire; Black and Gruwell 2004, entire; USBR 2005a, entire). Water management for hydropower or irrigation has augmented natural flows in some streams, especially in late summer when natural stream flows were historically low (*e.g.,* Diamond Fork occurrence (Jordan AU), Lower Green River AU). This augmentation has expanded the amount of streamside habitat with suitable hydrology to support large numbers of Ute ladies'-tresses (Ward and Naumann 1998, pp. 25–26; Black and Gruwell 2004, pp. 8–9).

Ute ladies'-tresses plants are frequently encountered along streams and canals and in wet hay pastures in the Uinta Basin, Utah (Lower Green River AU), even though an extensive irrigation canal system was constructed in the early 1900s and natural streams are nearly dry all summer (Fertig et al. 2005, pp. 19, 44, 48; Goodrich 2005, entire; Jordan 2006, entire). The species has colonized wetlands left behind when peat was mined, and it occurs in drainage ditches alongside roads and railroad tracks (Fertig et al. 2005, pp. 16, 19, 32–33, 36–37, 45, 50, 52).

In growing urban areas, primarily in the urban areas of Utah and Colorado (see Urban Development, above) and possibly Nevada, an increased demand for municipal water and conversion of irrigation water to municipal water may lead to dewatering of Ute ladies'-tresses habitat (Riedel 2004, p. 2). One occurrence in Utah (Jordan AU) may be extirpated due to dewatering in the last decade, although it is possible dormant plants remain and could emerge if the hydrological regime again becomes suitable for Ute ladies'-tresses (Fertig et al. 2005, p. 82; Trater 2020, pers. comm.; Service 2024, p. 47). Dewatering may exacerbate the effects of drought and climate change.

We incorporated this stressor in our evaluation of current resiliency by assessing the hydrologic condition of occurrences (Service 2024, pp. 97–98). We incorporated this stressor in our evaluation of future resiliency by evaluating projected changes in drought severity and frequency at the occurrence and AU levels (Service 2024, pp. 129–134).

Agriculture

Agricultural practices have the potential to result in the loss of plants and habitat under cultivation (croplands) and with herbicide use, or they can support or maintain suitable habitat conditions for Ute ladies'-tresses under managed pastures (irrigated

pastures with some mowing or haying) or irrigation canals (Fertig et al. 2005, pp. 83, 85; Service 2024, p. 92). Some occurrences in five AUs (Great Salt Lake, Jordan, Lower Bear, Lower Green River, South Platte) are in irrigated pastures that function as wet meadow habitat and support the species (Service 2024, pp. 43–51; Fertig et al. 2005, pp. 13, 17, 19). Conversely, negative impacts to Ute ladies'-tresses have also been documented along irrigation canals that have been converted to water pipelines in one AU (Lower Green River), but these impacts are localized and have not resulted in the total loss of an occurrence (ULT Tech 2021, entire; Service 2024, p. 51). Non-Federal landowners actively manage irrigation water at two occurrences in Utah and Colorado (Lower Bear and South Platte AUs) to support the Ute ladies'-tresses on lands used for the species' preservation and for recreation, respectively (Riedel 2004, p. 2; Bear River Land Conservancy 2014, pp. 5–14; Service 2024, p. 49).

We incorporated this stressor in our evaluation of current resiliency by assessing the agricultural land use, habitat condition, and hydrological condition of occurrences (Service 2024, pp. 96–121). For future resiliency, we considered the effects of this stressor as part of our evaluation of projected changes in land use and anthropogenic effects (Service 2024, pp. 134–135).

Livestock Grazing

Livestock grazing, haying, and mowing have the potential to result in the loss of plants or flowers but can also result in beneficial effects by removing competing vegetation and maintaining an open canopy (Fertig et al. 2005, pp. 70, 79, 81; Sipes et al. 1995, pp. 24–25; Service 2024, p. 91). Ute ladies'-tresses appears to need these types of disturbances in meadow or spring habitats that experience less frequent disturbance events than rivers and streams (Arft 1995, pp. 122–153, 157–159; Allison 2001, pp. 1–10; Fertig et al. 2005, pp. 81–82). The results of Ute ladies'-tresses population projections in wet meadow habitat conditions under various management practices identified the importance of livestock grazing or grazing and mowing to support population persistence (Arft 1995, pp. 122–153, 157–159; Hazlett 1996, p. 7). Long-term studies of wet meadow habitat in Colorado found that Ute ladies'-tresses' recruitment and flowering density were significantly higher in grazed and mowed habitat compared to undisturbed habitat (Arft 1995, pp. 122–153, 157–159; Allison 2001, pp. 1–10). Winter grazing or mowing also appears to be beneficial in reducing the negative impact of field vole (*Microtus pennsylvanicus* and *M. ochrogaster*) herbivory on Ute ladies'-tresses fruit and seed production by removing vegetation and litter that support vole populations (Arft 1995, pp. 153, 157–159; Fertig et al. 2005, p. 70). Where wet meadow habitat is protected and managed for Ute ladies'-tresses in Colorado and Utah (South Platte and Lower Bear AUs), managers recommend timed haying, livestock grazing, and irrigation practices to maintain optimal habitat conditions and minimize impacts to flowering plants (Allison, 2001, pp. 1–3; Bear River Land Conservancy 2014, pp. 7–8, 14, 16; Service 2024, pp. 49, 84). Excessive or improperly timed livestock grazing, haying, and mowing may negatively impact the species (Fertig et al. 2005, p. 81; Service 2024, p. 35).

We incorporated this stressor in our evaluation of current resiliency by assessing the land use and habitat condition of occurrences (Service 2024, pp. 96–121). For future resiliency, we considered the effects of this stressor as part of our evaluation of projected changes in land use (Service 2024, pp. 134–135).

Recreation

Recreation has the potential to result in plant damage and mortality through trampling as well as provide a land use that conserves Ute ladies'-tresses habitat (Service 2024, p. 91). Many occurrences in Colorado, Nevada, Utah, Idaho, and Washington (Lower Colorado-Lake Mead, Jordan, Upper Green, South Platte, Snake Headwaters, and Upper Columbia AUs) are located on lands where recreation occurs; however, recreation was only identified as a current or potential stressor at a few occurrences in Colorado, Idaho, and Utah where trampling from fishing, boating, and off-road vehicle access has been reported (Fertig et al. 2005, pp. 35–53; Service 2024, p. 63).

We incorporated this stressor in our evaluation of current resiliency by assessing the land use and habitat condition of occurrences (Service 2024, pp. 96–121). For future resiliency, we considered the effects of this stressor as part of our evaluation of projected changes in land use (Service 2024, pp. 134–135).

Invasive Plants

Invasive plants have the potential to directly compete with Ute ladies'-tresses plants for water, nutrients, and sunlight (Service 2024, p. 94). Some invasive plants are adapted to the same early- to mid-seral successional habitats as Ute ladies'-tresses and are highly effective competitors. Fourteen invasive plants commonly occur with Ute ladies'-tresses, including upland plants such as thistles (*Cirsium* spp.) and leafy spurge (*Euphorbia esula*), wetland plants such as purple loosestrife (*Lythrum salicaria*) and reed canary grass (*Phalaris arundinacea*), and woody invasives such as tamarisk (*Tamarix* spp.) and Russian olive (*Elaeagnus angustifolia*) (Murphy 2001, pp. 19–20; Naumann 2003, entire; Murphy 2004, p. 10; Fertig et al. 2005, p. 83; Jones 2006, entire).

While invasive plants are present in Ute ladies'-tresses habitat, and some occurrences may have been partially overtaken by invasive plants, the best available information indicates this stressor has not resulted in Ute ladies'-tresses' plant mortality or the extirpation of occurrences (Fertig et al. 2005, pp. 45–47, 50; Service 2024, p. 94).

We considered this stressor in our evaluation of current resiliency as part of our occurrence habitat condition assessment (Service 2024, pp. 96–121). For future resiliency, we considered the effects of this stressor as part of our evaluation of projected changes in land use and effects of climate change (Service 2024, pp. 134–135).

Collection

We identified overcollection as a threat to Ute ladies'-tresses in the final listing rule (57 FR 2048 at 2051 and 2052, January 17, 1992). Despite the one documented instance of ''essence of *Spiranthes*'' derived from Ute ladies'-tresses flowers in the late 1990s, the threat of collection is low, given that the species is less showy than tropical orchids and other *Spiranthes* species are available for purchase (Kratz 1998, entire; Fertig et al. 2005, p. 86; Alaskan Essences 2024, entire; Carnivorous Plant Nursery 2024, entire; Microsoft Bing 2024, entire; Plant Delights Nursery 2024, entire). There is no evidence that collection is currently impacting Ute ladies'-tresses or is likely to do so in the future.

Vegetative Succession

Vegetative succession has the potential to change the habitat condition and suitability for Ute ladies'-tresses due to lack of sunlight and competition for resources (Fertig et al. 2005, p. 84; Service 2024, p. 94). Flooding is the primary disturbance along river and stream corridors that influences vegetative succession. Water level fluctuations in combination with land use activities such as mowing and grazing, and occasionally fire, appear to be the primary disturbances in

lakeshore, wet meadow, and spring habitats (Fertig et al. 2005, p. 32).

The extent of woody encroachment and late-seral successional habitats within Ute ladies'-tresses occurrences is variable and site-specific depending on the degree to which the hydrologic and disturbance regimes have been altered. The best available information indicates that vegetative succession is currently only affecting individual plants and portions of an occurrence (Fertig et al. 2005, p. 66; Black 2006, entire). The primary driver of vegetative succession is the hydrologic regime or land use associated with the habitat. Therefore, this stressor is not having a population-level effect to Ute ladies'-tresses on its own unless vegetative succession is associated with a major change to the hydrology or land use of the occurrence. We incorporated this stressor in our evaluation of current resiliency by assessing the habitat condition of occurrences (Service 2024, pp. 113–116). For future resiliency, we evaluated projected changes to the vegetative resiliency metric based on projected land use changes (Service 2024, pp. 139–195).

Disease or Predation

Predation (herbivory) on Ute ladies'-tresses was mentioned in the final listing rule because excessive livestock grazing was thought to be detrimental, and plants are highly palatable and preferentially grazed by small herbivores (57 FR 2048 at 2051, January 17, 1992). Although livestock grazing was categorized as a stressor under Factor C at the time of listing, we consider the effects of livestock grazing to be better characterized by Factor A (see ''Livestock Grazing,'' above). Herbivory of flowers and inflorescences (entire flowering stems) by field voles has been documented at a few occurrences in Colorado and Utah (Arft 1995, pp. iv, 79–87, 103–104, 113–117; Sipes et al. 1995, pp. 9–10; Heidel 2001, p. 8; Black and Gruwell 2004, p. 10; Fertig et al. 2005, pp. 89–90; Black 2006, entire). Additional monitoring indicates that winter livestock grazing or mowing maintains early seral habitat conditions favored by Ute ladies'-tresses and reduces vole herbivory by removing thatch buildup, which serves as a protective cover favored by voles, in the habitat (Arft 1995, pp. 79–87, 103–104, 113–117; Sipes et al. 1995, pp. 9–11; Peles and Barrett 1996, entire; Skopec et al. 2017, pp. 5–6). The best available information indicates that vole herbivory occasionally impacts individual plants and may locally affect some populations; however, it is seasonal in nature and unpredictable (Skopec et al. 2017, pp. 5–6; Andreassen et al. 2021, pp. 601–605). Most occurrences along rivers and streams occur in early- to mid-seral habitat conditions with little to no thatch buildup, and most meadow or seep habitats are grazed or mowed to remove thatch buildup. We did not find that vole herbivory occurs at spatial and temporal scales large enough to affect the overall status of Ute ladies'-tresses given the plant's current status. We are not aware of any issues or potential stressors related to disease or insect predation. Therefore, we did not include this stressor in our evaluation of current and future resiliency.

Drought

Drought has the potential to result in the loss of Ute ladies'-tresses plants; changes in vegetation, hydrology, and soil saturation; and temporary or permanent loss of habitat depending on the severity and duration of drought conditions (Service 2024, p. 92). Water management has ameliorated summer drought conditions in some river corridors (see ''Water Management,'' above), but increases in municipal water use (dewatering or loss of irrigation water) could exacerbate the effects of drought in Ute ladies'-tresses habitat (Fertig et al. 2005, p. 85).

The best available information indicates that this stressor is not having a population-level effect to Ute ladies'-tresses. Ute ladies'-tresses tolerates a range of soil moisture as well as drought conditions, and, while drought conditions may temporarily reduce the number of flowering plants, Ute ladies'-tresses is able to remain dormant during periods of drought. The species' reliance on mycorrhizae may also mitigate the effects of drought stress (Ahluwalia et al. 2021, p. 7). The hydrology of its wetland habitat likely buffers the effects of minor reductions in precipitation or available water. We do not have a clear understanding of how Ute ladies'-tresses responds to severe or extreme droughts (defined as -3.0 or less on the Palmer Drought Index) (Dai et al. 2023, p. 1). However, we assume that an increase in the frequency of severe and extreme droughts will have a negative impact on the species. Therefore, we incorporated this stressor in our evaluation of current resiliency by assessing the hydrologic condition of occurrences (Service 2024, pp. 129–134). We incorporated this stressor in our evaluation of future resiliency based on the frequency of severe and extreme droughts at the occurrence level as part of the climate change stressor, which is discussed below (Service 2024, pp. 113–116).

Climate Change

Climate change has the potential to impact Ute ladies'-tresses if the frequency of severe and extreme droughts increases in the future (see ''Drought,'' above), and it may place an added stress on the species and its habitat, particularly when other stressors are present. We used the Standardized Precipitation Evaporation Index (SPEI) that allowed us to project drought severity and frequency at the occurrence level, and we used a precipitation-evaporation model ensemble (of 20 models) to evaluate how annual moisture availability is projected to change at the AU level (Service 2024, pp. 132–134). These models allowed us to evaluate future hydrologic conditions at the occurrence level, and the projected changes in water availability at the AU level. The SSA report describes other models and their limitations in detail (Service 2024, pp. 131–133). We used two different emission scenarios, a stabilization emission scenario using representative concentration pathway (RCP) 4.5 and a rising greenhouse gas emissions scenario using RCP 8.5 developed by the Intergovernmental Panel on Climate Change (IPCC).

The SPEI index accounts for precipitation and temperature changes that are useful indicators for detecting and measuring drought severity and duration within a variety of habitats and over a range of climate projections (Vicente-Serrano et al. 2010, entire). For occurrences, we used the SPEI index data for the spring and summer months (March through August) that are important for plant growth and reproduction to calculate and compare the historical (1980–2019) and future (2023–2074) decadal frequency of severe and extreme droughts (North Central Climate Adaptation Science Center (NC CASC) 2022, data set; Service 2024, pp. 132–134). The results of our evaluation indicate that the frequency of severe or extreme droughts during the spring and summer months varies across the species' range. At most occurrences, drought frequency is projected to increase by at least one but fewer than three additional severe or extreme droughts per decade; at some occurrences, drought frequency is projected to remain similar to or slightly increased from the historical frequency; and several occurrences project a slight decrease in drought frequency under one or both climate scenarios. Northern Utah, Idaho, and Washington are projected to generally remain stable or even see slight decreases in severe and extreme drought frequencies under both

scenarios. Occurrences along the southern part of the range, as well as those in Montana, are projected to see the greatest increase in drought severity and frequency. Lower elevation occurrences in desert ecosystems see the most extreme increases overall, and are more vulnerable to extirpation (Service 2024, pp. 198–199).

The precipitation-evaporation model ensemble accounts for larger scale changes to regional water availability (*e.g.,* dry getting drier, wet getting wetter) that we applied to the AU level as a proxy for future changes to the amount of potentially suitable habitat for Ute ladies'-tresses (Service 2024, pp. 134–136). While we do not know exactly how the amount of potentially suitable habitat will change in response to regional or watershed changes in water availability, we assumed that the amount of potentially suitable habitat within an AU would not change if future water availability in an AU remained within one standard deviation of historical levels. We compared the historical (1980–2020) and future (2020–2074) water availability in AUs. We found there was no meaningful change in water availability from historical levels under the two emission scenarios to indicate a decline in the amount of potentially suitable habitat (Willey 2024, entire; Service 2024, pp. 134–136).

Both intermediate and high emission scenarios (RCP 4.5 and 8.5) indicate that the range of Ute ladies'-tresses will be warmer and drier throughout the southern part of the range and warmer but with similar or slightly increased precipitation in northern Utah, Idaho, and Washington State in the future (through 2074) compared to historical conditions (Alder 2022, entire; Service 2024, pp. 13, 198). The frequency of severe or extreme droughts is expected to increase throughout most, although not all, of Ute ladies'-tresses' range. There is substantial uncertainty in how Ute ladies'-tresses will respond to more frequent severe or extreme droughts in many AUs within its range. When we considered characteristics that contribute to its ability to adapt to changing climate conditions, Ute ladies'-tresses has many attributes indicating moderate to high levels of adaptive capacity; these attributes include the species' large range occupying 12 ecoregions, its variable dispersal ability and moderately high dispersal distance along waterways, its general habitat requirements, and its flexible ability to reduce its exposure to climate stressors by remaining dormant during unfavorable conditions (Thurman et al. 2020, entire; Service 2024, pp. 123–129). We incorporated this stressor in our evaluation of future resiliency as part of the combined results of climate change and the human population change stressor in the SSA report and below (see *Future Scenarios and Future Condition,* below; Service 2024, pp. 129–199).

Human Population Change

Human population change within the range of Ute ladies'-tresses may increase the negative effects of anthropogenic stressors and environmental stressors to the species. The future rate and location of these changes is unclear, but human population growth is projected to increase at a regional scale within the species' range in the western United States (Weldon Cooper Center for Public Service 2024, entire).

We incorporated this stressor in our evaluation of future resiliency by evaluating the projected loss of Ute ladies'-tresses habitat in occurrences (Service 2024, pp. 129–136). We report the combined results of climate change and the human population change stressor in the SSA report and below (*see Future Scenarios and Future Condition,* below; Service 2024, pp. 129–199).

Current Condition

To assess the current condition of Ute ladies'-tresses across its extensive range, we broke the range into 18 smaller analytical units (AUs) based on USGS 6-digit hydrological unit code (HUC–6) watershed basins in consultation with species experts (see table 1 below; Jones et al. 2022, pp. 2, 5; Service 2024, pp. 26–28). This watershed scale provides a biologically meaningful delineation of areas where regular gene flow likely occurs between occurrences (Service 2024, pp. 23–26). As discussed above, we consider Ute ladies'-tresses AUs to be surrogates for populations (see Background, above). A map of these AUs is available in the SSA report (Service 2024, p. 4, figure 1).

In our SSA report, we evaluate current condition by examining current levels of resiliency in the 18 extant Ute ladies'-tresses AUs and implications for redundancy and representation. Here, we summarize our evaluation of the current condition for the resiliency, redundancy, and representation of Ute ladies'-tresses. Additional detail regarding our analysis is provided in the SSA report (Service 2024, pp. 100–127).

Resiliency

We describe the resiliency for each of the 18 AUs in terms of the demographic and habitat factors needed by Ute ladies'-tresses (Service 2024, pp. 93–96). We developed a categorical model to calibrate resiliency based on the range of demographic and habitat conditions in each AU. We first identified resource or demographic factors that contribute to the species' resiliency; these factors align with the individual resource needs and population-level needs we identified in the SSA analysis. We then defined threshold values for each identified resource or demographic factor that represent high, moderate, or low levels of that factor. Finally, we evaluated whether the current levels of each resource or demographic factor in a population fall within the predetermined thresholds for a high, moderate, or low score for the category; we then averaged these scores for each category to develop an overall current resiliency score for each population.

For Ute ladies'-tresses, our categorical model assessed the resiliency of each AU by evaluating (1) hydrologic condition, a qualitative evaluation of the hydrologic regime; (2) vegetative habitat condition, a qualitative evaluation of floral resources for Ute ladies'-tresses pollinators and successional stage; (3) abundance, the number of occupied occurrences within the AU; (4) potential habitat availability, the percentage of modeled suitable habitat within the AU; and (5) connectivity, the number of occurrences connected by modeled suitable habitat. We selected these habitat and demographic factors based on their importance to the species' resiliency and because we could evaluate them relatively consistently across all 18 AUs.

Resiliency categories, thresholds, and scores were established based on the best available information and professional opinion of species experts. Hydrologic condition was based on expert opinion, available survey reports, and inspection of aerial imagery to assess surface or subsurface water in the habitat and the frequency of extreme flooding or year-round inundation. Vegetative habitat condition was based on expert opinion and available survey reports to assess whether the condition was good, moderate, or poor for Ute ladies'-tresses. Abundance was based on State heritage program database information and available survey reports to identify the number of extant occurrences within AUs. Percentage of potential habitat availability and connectivity (the number of occurrences connected by potentially suitable habitat) within each AU were based on Service modeled suitable habitat (Service 2024, pp. 96–99, appendix I). We applied equal weight to four factors (hydrologic condition, vegetative habitat condition, abundance, and connectivity)

and applied one-half the weight (0.5) to the potential habitat availability factor because we have less confidence in the results compared to the other factors, as the potential habitat availability model only represents the potential for the species to recolonize into new areas following a possible extirpation and may overpredict potential habitat in AUs.

There are 18 Ute ladies'-tresses AUs comprised of 62 occurrences, and according to our current condition analysis in the SSA report, 5 have high resiliency, 8 have moderate resiliency, and 5 have low resiliency (see table 1, below; Service 2024, pp. 122–123). The 13 AUs with high and moderate resiliency maintain moderate or high hydrologic condition; moderate or high population abundance (the exception is Lower Bear AU with low abundance); and a range of scores for vegetative habitat condition, connectivity, and potential habitat availability. The 13 AUs with high or moderate resiliency are distributed across the species' range, are present in all 8 U.S. States and Canada, and are present in 10 of the 12 ecoregions (see table 1, below). Five AUs have low resiliency due to low abundance and two or more additional factors with low scores. Notably, all 18 AUs have moderate or high resiliency scores for hydrological condition. The 13 AUs with high or moderate resiliency are at less risk from potential stochastic events, such as climatic variation, than the AUs with low resiliency.

TABLE 1—CURRENT CONDITION RESILIENCY RANKINGS FOR UTE LADIES'-TRESSES AUS

AU name (States * or Canada)	Number of extant occurrences	AU resiliency	Level-III ecoregions
Cheyenne (WY, SD, NE)	1	Low	Northwestern Great Plains.
Colorado Headwaters (CO)	2	Moderate	Southern Rockies.
Great Salt Lake (UT, NV)	1	Low	Central Basin and Range.
Jordan (UT)	5	High	Central Basin and Range, Wasatch and Uinta Mountains.
Lower Bear (UT, ID)	1	Moderate	Central Basin and Range, Wasatch and Uinta Mountains.
Lower Colorado-Lake Mead (NV, UT, AZ)	1	Low	Wasatch and Uinta Mountains, Colorado Plateaus.
Lower Green River (UT, CO)	13	High	Central Basin and Range.
Missouri Headwaters (MT, WY)	9	High	Middle Rockies.
Niobrara (WY, SD, NE)	2	Moderate	High Plains.
North Platte (WY, NE, CO)	3	High	High Plains.
Snake Headwaters (ID, WY)	2	Moderate	Snake River Plain, Middle Rockies.
South Platte (WY, CO, NE)	6	Moderate	Southern Rockies, High Plains.
Upper Colorado-Dirty Devil (UT, AZ)	1	Low	Colorado Plateau.
Upper Columbia (WA, Canada)	6	Moderate	Columbia Plateau, North Cascades.
Upper Green (UT, CO)	2	High	Wasatch and Uinta Mountains, Colorado Plateau, Wyoming Basin.
Upper Missouri (MT)	2	Moderate	Middle Rockies.
Upper Snake (ID, WY, UT, NV)	4	Moderate	Snake River Plain, Middle Rockies.
Weber (UT, WY)	1	Low	Central Basin and Range.

* State abbreviations are Arizona (AZ), Colorado (CO), Idaho (ID), Montana (MT), Nebraska (NE), Nevada (NV), South Dakota (SD), Utah (UT), Washington (WA), and Wyoming (WY).

Redundancy

Redundancy describes the number and distribution of AUs, and the greater the number and the wider the distribution of the AUs, the better Ute ladies'-tresses can withstand catastrophic events. The plausibility of catastrophic events also influences species' redundancy; if catastrophic events are unlikely within the range of the species, catastrophic risk is inherently lower. We identified severe to extreme drought conditions as a plausible catastrophic event that may affect one or more population simultaneously. We evaluated the risk of this catastrophic event and its impact on species redundancy in our future scenarios (see *Future Scenarios and Future Condition,* below). Ute ladies'-tresses' redundancy is characterized by 18 AUs (watersheds) distributed across its large range; AUs are separated by the Northern and Middle Rocky Mountains, and distances of approximately 350 miles for the more isolated Upper Columbia AU. As we mentioned above, the 13 AUs with high or moderate resiliency are distributed across the species' range, are present in all 8 U.S. States and Canada, and are present in 10 of the 12 ecoregions. Thus, the 13 higher resiliency populations and their distribution help spread the risk of catastrophic drought conditions over a larger geographic area and contribute to the species' ability to withstand catastrophic events. We are aware of one AU (Upper Arkansas) that is extirpated in Colorado due to urban development (Service 2024, pp. 65–66, 100–109).

Representation

Ute ladies'-tresses exhibits considerable ecological diversity; the species is found in 3 different ecological classifications (Great Plains, North American Deserts, and Western Forested Mountains), 12 level-III ecoregions, and 7 habitat types (see Background, above). High genetic diversity was documented in populations located in six of the eight States within the species' range, and there is very little morphological variability across the range. The species has greater levels of representation than we previously understood at the time Ute ladies'-tresses was listed in 1992, because of our better understanding of the species, including more known occurrences and AUs, and a broader known distribution.

Future Scenarios and Future Condition

In our SSA report, we forecasted the resiliency of Ute ladies'-tresses AUs and the redundancy and representation of the species for approximately 50 years (to 2074) using a range of three plausible future scenarios. We relied on combined IPCC climate and land use projections out to 2074 (the timeframe for which they were available). These projections informed our evaluation of habitat loss from anthropogenic activities. This

timeframe encompasses approximately 2 to 3 generations of the species, the duration (30 years) of the applicable Federal land management plans by USFS and BLM, and the duration (50 years or more) of dam operation contracts or licenses. We can reasonably determine projected changes in the climate change and anthropogenic activities/stressors using geospatial data sets and the species' likely responses to those stressors within this 50-year timeframe (*i.e.,* the foreseeable future).

We developed three plausible future scenarios using three climate models that were downscaled to the Ute ladies'-tresses' AUs. By developing a range of plausible future scenarios, we assume that actual future conditions will likely fall somewhere between these three scenarios. We consider the driving factors of the species' viability to be two separate, but interconnected influences—the effects of anthropogenic activity related to loss of habitat from stressors that include urban development, water management, agriculture, recreation, and land conversion, and the effects of climate change influencing the amount of water available in a watershed. The primary negative influence of anthropogenic activity to AU resiliency is the loss of Ute ladies'-tresses plants and habitat, regardless of the particular anthropogenic stressor(s). We then used existing models and data to project the effects of climate change and anthropogenic activities on the demographic and habitat factors that influence resiliency, redundancy, and representation. We calculated the future resiliency score using the same methods as the current condition score. If anthropogenic activity was projected to cause extirpation of an occurrence (50 percent or more potential suitable habitat loss was projected), it was removed from the AU prior to the evaluation of climate change effects. If the AU future resiliency ranking fell below 0.9 (lowest possible original score), we assumed the AU would become extirpated (a condition lower than the low condition category and unlikely to be resilient to stochastic events) in the foreseeable future under that scenario.

For anthropogenic activity, we evaluated the projected loss of Ute ladies'-tresses habitat in occurrences based on changes in land use and land cover (Service 2024, pp. 134–136). We used USGS land cover projections out to 2074 that correspond to the three climate change and human population change scenarios (B1, B2, and A2) developed by the IPCC (Sohl et al. 2018, data set; USGS 2019, dataset). Detailed descriptions of each scenario are available in the SSA report (Service 2024, pp. 129–199). Scenario 1 (B1) represents a stabilization of emissions (RCP 4.5) and a slowed rate of human population growth. The B1 or stabilization climate scenario describes a global population that peaks in mid-century and declines thereafter under intermediate emissions. Scenario 2 (B2) represents the continuation of the current rate of human population growth into the future with technology mitigating some growth under high emissions (RCP 8.5), and Scenario 3 (A2) represents a largely unchecked population growth under high emissions (RCP 8.5) (IPCC 2000, pp. 9–11).

The USGS land cover projections identify changes on non-Federal lands because they have a higher risk of development and other anthropogenic stressors compared to Federal lands. This is consistent with our understanding of the development risk for the species' wetland habitats. We consider there to be a low risk of future development in Ute ladies'-tresses habitat on Federal lands, and we assumed no habitat loss from development on Federal lands in our future projections.

We consider the USGS emergent wetlands, woody wetlands, and hay or pasture land cover categories to represent suitable habitat for Ute ladies'-tresses, and we calculated the amount of habitat loss based on projected changes to those land cover categories. We assumed the loss of habitat if suitable habitat for Ute ladies'-tresses within an occurrence was converted to moderately or highly developed land or to cultivated cropland categories. If there was 50 percent or more suitable habitat loss within an occurrence, then we considered the occurrence to be extirpated.

Depending on the scenario, some occurrences in rapidly urbanizing areas are projected to be extirpated; however, there is very little habitat loss projected for most of the occurrences (Service 2024, pp. 139–199). In the B1 scenario, human population change and associated anthropogenic stressors were projected to result in the loss of three occurrences in Utah and Colorado (within the Jordan, Lower Green River, and South Platte AUs). In the B2 scenario, we project a loss of 10 occurrences in Utah, Colorado, Montana, and Idaho (within the Jordan, Lower Green River, Missouri Headwaters, South Platte, Upper Colorado-Dirty Devil, Upper Snake AUs). In the A2 scenario, we project a loss of 11 occurrences in Utah, Colorado, Nevada, Montana, and Idaho (within the Jordan, Lower Colorado-Lake Mead, Lower Green River, Missouri Headwaters, South Platte, Upper Colorado-Dirty Devil, Upper Missouri, Upper Snake AUs). For some occurrences, if they were projected to be extirpated because of a loss of hydrologic condition, we did not assess their projected extirpation risk from human activities.

As discussed above, we evaluated climate change effects to occurrence hydrologic condition using SPEI index projections of severe and extreme drought frequency out to 2074 (see ''Climate Change,'' above). We used SPEI index projections under intermediate emissions (RCP 4.5) for Scenario 1, and SPEI index projections under high emissions (RPC 8.5) for Scenarios 2 and 3. For each occurrence, we compared the historical and projected future decadal frequency (to 2074) of severe and extreme droughts within the species' range. We made no change to an occurrence's projected hydrologic or vegetative condition category if the drought frequency was projected to remain similar to the historical drought frequency (less than one additional severe or extreme drought per decade above the historical frequency). For all three scenarios, we reduced an occurrence's future hydrologic condition by one category (from high to moderate; moderate to low) if the drought frequency was projected to increase by 1 to 1.9 severe to extreme drought(s) per decade above the historical frequency, and by two categories if the frequency was projected to increase by 2 to 3 severe to extreme droughts per decade above the historical frequency.

For climate change effects to occurrence vegetative habitat condition, we assumed that there was no change in the condition category under intermediate emissions (RCP 4.5) for Scenario 1. However, we assumed that vegetative habitat condition would change the same amount as hydrologic condition for a given occurrence under the two high emissions scenarios, Scenarios 2 and 3 (Service 2024, p. 133).

In Scenario 1 (B1), anthropogenic activities are projected to increase in two States within the range; associated habitat loss would result in the extirpation of three occurrences in Utah and Colorado (within the Jordan, Lower Green River, and South Platte AUs). However, the extirpations of these occurrences do not affect the overall AU resiliency scores.

The frequency of severe and extreme droughts varies across the species' range. Small increases in decadal

drought frequency are projected for most occurrences in northern Utah, Idaho, and Washington, although a few occurrences in those States show a small decrease in drought frequency relative to current trends. The remaining States and Canada show a larger per decade increase in drought frequency (by approximately 1 to 2 more additional severe to extreme droughts per decade) at most occurrences. No occurrences were projected to have an increase of three or more severe to extreme droughts in any scenario. Occurrences in Montana and those at the southern edges of the range in Nevada and southern Utah are projected to see the largest increases in drought frequency. Projected climate change effects and associated declines in occurrence hydrologic condition result in the extirpation of five occurrences in Montana, Colorado, and Utah (within the Missouri Headwaters, South Platte, Upper Colorado-Dirty Devil AUs). The one extirpated occurrence in the Upper Colorado-Dirty Devil AU results in the extirpation of that AU, since that is the only occurrence in that AU.

We project the resiliency of 15 AUs will remain the same as current conditions, 2 AUs (Missouri Headwaters, North Platte) will drop from high to moderate overall resiliency, and 1 AU (Upper Colorado-Dirty Devil) will drop from low resiliency to extirpated (see table 2, below). Declines in AU resiliency were driven by climate change effects. Redundancy declines because 17 AUs remain and 1 is extirpated, and representation remains the same as current conditions in terms of represented ecoregions and habitat types.

Ute ladies'-tresses is projected to maintain 13 AUs with high or moderate resiliency in Scenario 1 (B1), and these AUs are at less risk from potential stochastic events, such as climatic variation, than the 4 AUs with low resiliency.

In Scenario 2 (B2), anthropogenic activities increase in four States within the range; projections of this stressor and associated habitat loss result in the extirpation of nine occurrences in Utah, Colorado, Montana, and Idaho (within the Jordan, Lower Green River, Missouri Headwaters, South Platte, and Upper Snake AUs).

The frequency of severe and extreme droughts is projected to increase in most AUs by one to less than three additional severe to extreme droughts per decade over current trends. Similar to Scenario 1, Utah, Idaho, and Washington experience the smallest increases in drought frequency, and in some cases smaller than the frequencies projected in Scenario 1, which is considered the less extreme climate scenario. However, occurrences in Montana and at the southern edges of the range in Nevada and southern Utah are projected to have the largest increases in drought frequency. Projected climate change effects and associated declines in occurrence hydrologic condition result in the extirpation of the Upper Colorado-Dirty Devil AU and two additional occurrences in Montana in the Missouri Headwaters AU.

We project the overall resiliency of 13 AUs will remain the same as the current condition, 2 AUs (Jordan, North Platte) will drop from high to moderate condition, 1 AU (Missouri Headwaters) will drop from high to low condition, 1 AU (South Platte) will drop from moderate to low condition, and 1 AU (Upper Colorado-Dirty Devil) will drop from low to extirpated condition (see table 2, below). Declines in AU resiliency were driven by anthropogenic activities in the Jordan AU, the combination of anthropogenic activities and climate change effects in the Missouri Headwaters and South Platte AUs, and climate change effects in the North Platte and Upper Colorado-Dirty Devil AUs. Redundancy declines because 17 AUs remain and 1 is extirpated, and representation remains the same as current conditions in terms of represented ecoregions and habitat types.

The increase in climate change and anthropogenic effects compared to current conditions under Scenario 2 has the potential to negatively impact vegetative condition. We expect dormant seedlings and plants to remain viable under this scenario and to support population resiliency. Despite some reduction in resiliency, Ute ladies'-tresses is projected to maintain 11 AUs with high or moderate resiliency in this scenario, and these AUs are at less risk from potential stochastic events, such as climatic variation, than the 6 AUs with low resiliency.

In Scenario 3 (A2), anthropogenic activities increase in 5 States within the species' range; associated habitat loss results in the extirpation of 11 occurrences in Utah, Colorado, Montana, Idaho, and Nevada (within the Jordan, Lower Green River, Missouri Headwaters, South Platte, Upper Snake, Upper Missouri, and Lower Colorado-Lake Mead AUs).

As in Scenario 2, more occurrences are projected to see increases of one to less than three additional severe to extreme droughts per decade over current trends, and these effects are compounded by more anthropogenic activity. Projected climate change effects and associated declines in occurrence hydrologic condition result in the extirpation of the Upper Colorado-Dirty Devil AU, as well as three occurrences in Colorado and Montana (within the South Platte and Missouri Headwaters AUs).

We project the overall resiliency of 11 AUs will remain the same as the current condition, 2 AUs (Jordan, North Platte) will drop from high to moderate condition, 1 AU (Missouri Headwaters) will drop from high to low condition, 2 AUs (South Platte and Upper Missouri) will drop from moderate to low condition, and 2 AUs (Upper Colorado-Dirty Devil and Lower Colorado-Lake Mead) will drop from low to extirpated condition (see table 2, below). Declines in AU resiliency were driven by anthropogenic activities in the Jordan and Lower Colorado-Lake Mead AUs; the combination of anthropogenic activities and climate change effects in the Missouri Headwaters, Upper Missouri, and South Platte AUs; and climate change effects in the North Platte and Upper Colorado-Dirty Devil AUs. Redundancy declines because 16 AUs remain and 2 are extirpated, and representation remains the same as current conditions in terms of represented ecoregions and habitat types.

The increase in climate change and anthropogenic effects compared to current conditions under Scenario 3 has the potential to negatively impact vegetative condition. We expect dormant seedlings and plants to remain viable under this scenario and to support population resiliency. Despite some reduction in resiliency, Ute ladies'-tresses is projected to maintain 10 AUs with high or moderate resiliency in this scenario, and these AUs are at less risk from potential stochastic events, such as climatic variation, than the 6 AUs with low resiliency.

TABLE 2—SUMMARY OF UTE LADIES'-TRESSES RESILIENCY FOR THE CURRENT CONDITION AND THREE FUTURE SCENARIOS

AU	Resiliency			
	Current condition	Future scenario 1	Future scenario 2	Future scenario 3
Cheyenne	Low	Low	Low	Low.
Colorado Headwaters	Moderate	Moderate	Moderate	Moderate.
Great Salt Lake	Low	Low	Low	Low.
Jordan	High	High	Moderate	Moderate.
Lower Bear	Moderate	Moderate	Moderate	Moderate.
Lower Colorado-Lake Mead	Low	Low	Low	Extirpated.
Lower Green River	High	High	High	High.
Missouri Headwaters	High	Moderate	Low	Low.
Niobrara	Moderate	Moderate	Moderate	Moderate.
North Platte	High	Moderate	Moderate	Moderate.
Snake Headwaters	Moderate	Moderate	Moderate	Moderate.
South Platte	Moderate	Moderate	Low	Low.
Upper Colorado-Dirty Devil	Low	Extirpated	Extirpated	Extirpated.
Upper Columbia	Moderate	Moderate	Moderate	Moderate.
Upper Green	High	High	High	High.
Upper Missouri	Moderate	Moderate	Moderate	Low.
Upper Snake	Moderate	Moderate	Moderate	Moderate.
Weber	Low	Low	Low	Low.

Under all three future scenarios, the overall resiliency of at least 11 AUs is projected to remain the same as the current condition. Declines in overall resiliency for the remaining AUs were driven by climate change in Scenario 1 and the combination of anthropogenic activities and climate change in Scenarios 2 and 3. Under all three future scenarios, Ute ladies'-tresses is projected to maintain at least 10 AUs with high or moderate resiliency, and these AUs are at less risk from potential stochastic events, such as climatic variation, than the AUs with low resiliency. AUs along large, mainstem rivers with multiple occurrences (Upper Green, Lower Green River, Upper Columbia, Upper Snake, Lower Bear, Niobrara, Colorado Headwaters) are the most resilient; they maintain their overall resiliency scores across all future scenarios despite projected declines in abundance and connectivity. The Upper Colorado-Dirty Devil AU in the southern part of the range is the least resilient and is projected to be extirpated in all three future scenarios due to climate change.

Under all three future scenarios, some genetic diversity within populations could be lost. However, even in the most pessimistic plausible scenario (Scenario 3), 16 AUs are expected to remain extant and ecological variation will continue to be represented by the 12 ecoregions and 7 habitat types across Ute ladies'-tresses' range.

We note that, by using the SSA framework to guide our analysis of the scientific information documented in the SSA report, we have analyzed the cumulative effects of identified threats and conservation actions on the species. To assess the current and future condition of the species, we evaluate the effects of all the relevant factors that may be influencing the species, including threats and conservation efforts. Because the SSA framework considers not just the presence of the factors, but to what degree they collectively influence risk to the entire species, our assessment integrates the cumulative effects of the factors and replaces a standalone cumulative-effects analysis.

See the SSA report (Service 2024, entire) for a more detailed discussion of our evaluation of the biological status of Ute ladies'-tresses and the stressors that may affect its continued existence. Our conclusions in the SSA report, which form the basis for the determination below, are based upon the best available scientific and commercial data.

Conservation Efforts and Regulatory Mechanisms

There are several regulatory mechanisms, as well as conservation efforts, that may minimize the effect of stressors or provide benefits to Ute ladies'-tresses. Due to the broad distribution of Ute ladies'-tresses in the United States and Canada, management of this species falls under numerous jurisdictions. Roughly 95 percent of the species' range occurs in the United States, with the remaining 5 percent of its range occurring in British Columbia, Canada. In the United States, approximately 37 percent of land where the species occurs is federally owned or managed by the BLM, USBR, USFS, Service, NPS, and DOD. Almost half of the land, approximately 47 percent, is under private ownership. There is a small amount (approximately 3 percent) of Ute ladies'-tresses habitat where the land ownership is not known. The remaining 13 percent of the species' range is on State and Tribal lands (Service 2024, p. 39).

International Regulatory Mechanisms

International trade in all orchids is regulated by the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES; 27 U.S.T. 1087, March 3, 1973), an international agreement ratified by most countries worldwide since 1975. The purpose of CITES is to regulate the international wildlife trade to safeguard certain species from over-exploitation. Ute ladies'-tresses is listed as an appendix II species of CITES and would remain an appendix II species if delisted under the Act because it is an orchid. Under CITES, exporters must obtain a permit for international shipment of specimens. Export permits for an appendix II species are issued only when the following findings are made: (1) a scientific finding of non-detriment (*i.e.,* data or expert scientific opinion on the biological status of the species indicating that the export is not likely to be detrimental to species survival); and (2) a finding that specimens were acquired legally (*i.e.,* evidence that specimens to be exported were not obtained in violation of any State, Federal, or other jurisdictional law). More information on CITES can be found at: *https://cites.org/eng/disc/what.php.*

In Canada, the Committee on the Status of Endangered Wildlife in Canada (COSEWIC) designated Ute ladies'-tresses as a schedule 1 endangered species under the Canadian Species at Risk Act (SARA) in November 2018, due to the high risk of extirpation

(COSEWIC 2018, entire). This designation provides protection from harming, killing, collecting, buying, selling, or possessing Ute ladies'-tresses on Federal Crown lands. In Canada, the species occurs on lands within an Ecological Reserve that are permanently protected and managed by British Columbia Parks for their biodiversity, and on lands within the Osoyoos Indian Reserve with no conservation status (COSEWIC 2018, pp. 43–44).

Federal Regulatory Mechanisms

Clean Water Act—The Clean Water Act (CWA) was designed, in part, to protect surface waters of the United States from unregulated pollution from point sources. The CWA provides some benefit to Ute ladies'-tresses through the regulation of discharge into surface waters through a permitting process; however, the historical threats to Ute ladies'-tresses habitat have not typically been associated with point sources of pollution, and the best available information indicates that pollution is not a stressor.

Under section 404 of the CWA, the U.S. Army Corps of Engineers (USACE) regulates the discharge of fill material into waters of the United States, including wetlands that meet certain jurisdictional requirements. In general, the term ''wetland'' refers to areas meeting the USACE's criteria of hydric soils, hydrology (either sufficient annual flooding or water on the soil surface), and hydrophytic vegetation (plants specifically adapted for growing in wetlands).

The USACE and the U.S. Environmental Protection Agency (EPA) amended the definition of ''waters of the United States'' as it applies to the CWA and the jurisdictional authority of the USACE on September 8, 2023 (88 FR 61964), to comply with a 2023 Supreme Court Decision, *Sackett* v. *Environmental Protection Agency.* Under the new definition, jurisdictional (that is, regulated under the authority of the CWA) wetlands are those wetlands adjacent to navigable waters defined as interstate waters, and relatively permanent, standing or continuously flowing bodies of water with continuous surface connection to certain other bodies of water (see 33 CFR 328.3(a)(1) and (a)(4), and 40 CFR 120.2(a)(4)); and jurisdictional ''waters of the United States'' include certain intrastate lakes and ponds (see 33 CFR 328.3(a)(5)). Under this definition of waters of the United States, Ute ladies'-tresses occurrences along interstate waters or along intrastate lakes, ponds, streams, or wetlands that are relatively permanent, standing or continuously flowing bodies of water with a continuous surface connection to certain waterbodies would be considered as occurring in jurisdictional waters/wetlands, and we expect the protections of the CWA to remain if we delist Ute ladies'-tresses under the Act. However, in some cases, occurrences in wet meadow, spring, or seep habitats that do not meet the definition would not be considered jurisdictional waters/wetlands under the CWA. This means the loss of indirect protections under the CWA for occurrences on non-Federal lands in the United States. Under the previous and new definition of ''waters of the United States,'' certain farming activities, ditches, artificially irrigated areas that would revert to dry land if irrigation ceased, and artificial lakes, ponds, or waterfilled depressions incidental to construction activity are not considered waters of the United States and are excluded from the CWA's section 404 regulations.

National Environmental Policy Act—Environmental review of potential effects of Federal actions is mandated under the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*). When NEPA analysis reveals significant environmental effects, the Federal agencies must disclose those effects to the public and consider mitigation that could offset the effects. These mitigations usually provide some protections for listed species. However, NEPA does not require that adverse impacts be mitigated, only disclosed. Therefore, it is unclear what level of protection would be conveyed to Ute ladies'-tresses through NEPA, in the absence of protections under the Act.

National Park Organic Act—Federal activities on National Park Service (NPS) lands are subject to the National Park Service Organic Act (54 U.S.C. 100101 *et seq.*). The Organic Act specifies that the NPS will promote and regulate the use of the National Park System (System) by means and measures that conform to the fundamental purpose of the System units, which purpose is to conserve the scenery, natural and historic objects, and wild life in the System units and to provide for the enjoyment of the scenery, natural and historic objects, and wild life in such manner and by such means as will leave them unimpaired for the enjoyment of future generations (54 U.S.C. 100101(a)).

The NPS manages Ute ladies'-tresses occurrences in Dinosaur National Monument along the Green River in northwestern Colorado (Upper Green and Lower Green River AUs) and a historical occurrence in Capitol Reef National Park in Utah (Fertig et al. 2005, pp. 74, 77–78, 82, 89–90; Hendricks 2005, entire; Service 2024, pp. 67, 71, 84–85). For listed species, NPS provides habitat protections from conflicting land use; however, the NPS does not control the hydrology of the Green or Fremont Rivers. We expect habitat protections to continue along the Green River if we delist Ute ladies'-tresses based on the regulatory mechanisms provided by the Organic Act.

National Wildlife Refuge System Improvement Act—As directed by the National Wildlife Refuge System Improvement Act (Pub. L. 105–57), Service refuge managers have the authority and responsibility to protect native ecosystems, fulfill the purposes for which an individual refuge was founded, and implement strategies to achieve the goals and objectives stated in management plans. In the Lower Green River AU, Browns Park National Wildlife Refuge contained habitat for Ute ladies'-tresses along the Green River in northwestern Colorado upstream of Dinosaur National Monument as recently as 1999. Since then, flood and scour events have reduced the amount of occupied and suitable Ute ladies'-tresses habitat on the refuge (Horne 2024, pers. comm.). Browns Park National Wildlife Refuge's comprehensive conservation plan (CCP) is a land management plan that directs the protection and restoration of riparian and wetland habitats, including Ute ladies'-tresses habitat on the refuge (Service 1999, p. 22). Browns Park National Wildlife Refuge will continue to protect riparian and wetland habitats that include Ute ladies'-tresses habitat regardless of the Federal listing status of Ute ladies'-tresses (Horne 2024, pers. comm.).

In addition to specific protections for Ute ladies'-tresses provided under CCPs, the species is permanently protected by the mission of the National Wildlife Refuge System to administer a national network of lands and waters for the conservation, management, and where appropriate, restoration of the fish, wildlife, and plant resources and their habitats within the United States for the benefit of present and future generations of Americans (16 U.S.C. 668dd(a)(2)).

National Forest Management Act—Federal activities on U.S. Forest Service (USFS) lands are subject to the National Forest Management Act of 1976 (NFMA; 16 U.S.C. 1600 *et seq.*). The NFMA requires the development and implementation of resource management plans to guide the maintenance of ecological conditions that support natural distributions and abundance of species and not contribute to their extirpation.

The USFS manages Ute ladies'-tresses occurrences in the Ashley National Forest in northeastern Utah (Lower Green River AU), the Uinta-Wasatch Cache National Forest in northcentral Utah (Jordan AU), and the Caribou-Targhee National Forest in Idaho (Snake Headwaters AU) (Service 2024, pp. 47, 51, 61). Guidance for conservation of Ute ladies'-tresses is included in the Caribou-Targhee, Uinta, and Ashley National Forest plans (USFS 1997, p. III–14; USFS 2003, pp. 2–6, 5–51–5–53; USFS 2023, pp. 20–21, 54, 90, 93). The Uinta-Wasatch Cache National Forest designated the portion of the Diamond Fork Creek occurrence as a ''riparian habitat conservation area class I,'' which affords the highest level of protection (300-ft (91-m) avoidance buffer) for Ute ladies'-tresses in that area (USFS 2003, pp. D–1, D–2).

If we delist Ute ladies'-tresses, the species may still be recognized as a USFS species of conservation concern whereby the agency is directed to provide ecological conditions necessary to maintain viable populations of the species (77 FR 21162, April 9, 2012; 36 CFR 219.9; Hayward et al. 2016, pp. 8, 21–28). The USFS in each respective region has the authority to designate Ute ladies'-tresses as regional forester sensitive species (RFSS), which is similar to a USFS species of conservation concern (77 FR 21162 at 21175, April 9, 2012; 36 CFR 219.9(c)). If, in the future, Ute ladies'-tresses undergoes a downward trend and its viability is a concern, the USFS has the authority to designate it as a species of conservation concern. In addition, if delisted, Ute ladies'-tresses occupying riparian habitats on USFS lands will continue to receive levels of protection for riparian habitats identified in the forest plans (USFS 1997, pp. III–9–III–12; USFS 2003, pp. 3–2–3–5, 3–9–3–10, 3–14–3–15, 3–22, 3–25–3–27, D–1, D–2; USFS 2023, pp. 17–18, 46, 50, 53–54, 92).

Federal Land Policy and Management Act—The Federal Land Policy and Management Act (FLPMA; 43 U.S.C. 1701 *et seq.*) applies to the BLM with regard to the conservation and use of public lands under their management. The BLM manages Ute ladies'-tresses occurrences in Colorado, Utah, Idaho, Washington, and Wyoming (Colorado Headwaters, Lower Colorado-Lake Mead, Upper Colorado-Dirty Devil, Lower Green River, Upper Green, Snake Headwaters, Upper Snake, Upper Columbia, North Platte, and Cheyenne AUs) (Fertig et al. 2005, pp. 38–55; Service 2024, pp. 84–85).

Guidance for Ute ladies'-tresses conservation is included in some BLM resource management plans (RMPs) that include surveys, monitoring, avoidance buffers, and invasive species control (BLM 2020, pp. F–24–F–25; BLM 2015a, appendix J; BLM 2000, pp. 15–17; BLM 2007, appendix Z; BLM 2008a, appendix 14; BLM 2010, appendix T; BLM 2014, appendix P; BLM 2015b, appendix K; BLM 2015c, appendix K; BLM 2015d, appendix K; BLM 2016, appendix 28; BLM 2023a, pp. 3–12, 3–13, and 4–81–4–82; Carroll 2005, entire).

The one extant occurrence along Deer Creek in the Upper Colorado-Dirty Devil AU is located in the Grand Staircase National Monument in Utah, established in 1996 to preserve geologic, archaeologic, and ecological communities and provide for scientific research, education, and exploration (Presidential Proclamation 6920, September 18, 1996; BLM 2020, p. F–24–F–25). Occurrences in the Upper Snake River, Idaho (Upper Snake AU), are located along the floodplain of the Snake and Henry's Fork Rivers. The Snake River area of critical environmental concern (ACEC) includes 21,954 ac (8,884 ha) of BLM-managed public lands designated to protect and conserve riparian-wetland habitat. This ACEC is the top priority wetland in the State of Idaho, and we consider it to contain the highest-quality cottonwood riparian zone in the western United States (BLM 1985, pp. 25–26; Fertig et al. 2005, pp. 38–44; Velman 2005, entire; BLM 2023b, pp. 8–9; BLM 2023c pp. 90–91). Occurrences in the Green River (Lower Green River AU) are found in the Browns Park ACEC in Utah; the ACEC comprises 18,480 ac (7,479 ha) and protects high value scenery, wildlife habitat, and cultural resources (Fertig et al. 2005, p. 46; BLM 2008b, p. 36). The protections provided by ACEC designations are not contingent upon the species' federally listed status. The BLM's ACECs do not have an expiration date, and removing an ACEC designation is not simple. A withdrawal of an ACEC can be made only by the Secretary of the Interior (Secretary) or, if delegated by the Secretary, an individual in the Office of the Secretary who has been appointed by the President, by and with the advice and consent of the Senate (43 U.S.C. 1714(a)). The Snake River and Browns Park ACECs were designated to protect multiple species and resources in addition to Ute ladies'-tresses. Therefore, the ACEC designations will not change under the current BLM RMP, even if Ute ladies'-tresses is delisted.

Even without the protections of the Act, Ute ladies'-tresses orchid would remain a BLM sensitive species for at least 5 years (BLM 2008c, pp. 36, 47). The BLM in each respective State has the authority to designate Ute ladies'-tresses as a BLM sensitive species, which would provide protections equivalent to a Federal candidate species (BLM 2008c, pp. 43, 47). If, in the future, Ute ladies'-tresses undergoes a downward trend and its viability is at risk such that it meets the definition of a BLM sensitive species, the BLM has the authority to designate it as a BLM sensitive species (BLM 2008c, pp. 36–37).

If delisted, Ute ladies'-tresses occupying riparian habitats on BLM lands would also receive the levels of protection for riparian habitats identified in the RMPs, including avoidance buffers, livestock grazing provisions, and invasive species control (BLM 1985, p. 39; BLM 2000, pp. 8–12, 15–18, 37–40, 45–49, 54, 61; BLM 2007, pp. 2–10, 2–18–2–24, 2–40, 2–44; BLM 2008a, pp. 2–19, 2–35, 2–42, 2–46–2–50, and appendix 14; BLM 2008b, pp. 44, 113–115; BLM 2010, pp. 2–24–2–25, 2–30, 2–33–2–38, 2–45–2–49, 2–60, and appendix T; BLM 2014, pp. 18–19, 39–41, 46–48, 52, 58, 67, 98–99; BLM 2015a, pp. 33–48, and appendices B and J; BLM 2015b, pp. 6, 10, 32, 36–37, 47, 54, 59, 62, 73, 75–76, 85, 86, 97, 101–102, 106, 117–118, 125–126, 148–150, 161, 179–180; BLM 2015c, pp. 5, 27, 33–34, 42–43, 55, 60, 72, 75–76, 81, 85, 93, 105, 115, 121–123; BLM 2015d, pp. 5, 33–34, 42–43, 55, 60, 71, 74–76, 80, 84, 91, 103, 115, 126–128; BLM 2016, pp. 1–5–1–7, 2–3, 2–15–2–19, 2–25, 2–41–2–43, 2–55, 2–65–2–66, and appendix 28; BLM 2020, pp. ROD–17, ARMPs-14–15, C–16–C–17, C–20, F–9–F–11, F–25; BLM 2023a, pp. 2–14, 2–16–4–231).

Reclamation Act of 1902—The U.S. Bureau of Reclamation (USBR) is responsible for the management and development of many large Federal dams, water diversion structures, and water storage project construction in the western United States subject to the Reclamation Act of 1902 (Pub. L. 57–161; 43 U.S.C. 371 *et seq.*), and section 4007 of the Water Infrastructure Improvements for the Nation Act (WIIN Act, Pub. L. 114–322; 43 U.S.C. 390b note). The USBR has the authority to manage water flows and water releases along the Green River in Colorado and Utah, and the South Fork Snake River in Idaho. The USBR has delegated its authority in some areas to commissions (*e.g.,* the Utah Reclamation Mitigation and Conservation Commission (URMCC)) or Water Conservation Districts to manage smaller rivers such as the Provo, Duchesne, and Diamond Fork Rivers in Utah.

The USBR and other cooperating agencies have implemented management actions to benefit federally listed fish in river corridors where Ute ladies'-tresses occurs, and we expect these management actions to continue if Ute ladies'-tresses is delisted. The USBR, commissions, or Water Conservation Districts manage peak and base flows to support a more natural hydrograph and contribute to the creation of wetland habitats to support conservation of federally listed and native fish species such as the humpback chub (*Gila cypha*), Colorado pikeminnow (*Ptychocheilus lucius*), razorback sucker (*Xyrauchen texanus*), June sucker (*Chasmistes liorus*), and bull trout (*Salvelinus confluentus*). Fish conservation actions indirectly benefit Ute ladies'-tresses by creating suitable habitat and allowing a more natural hydrograph that allows for periodic flood and scour events to maintain early- to mid-seral habitat conditions.

Examples of management actions taken by the USBR include: (1) In the Upper Green and Lower Green River AUs, as part of the Upper Colorado River endangered fish recovery program (UCRRP) established in 1988, the USBR manages peak and base flows of the Green River to support a more natural hydrograph and contributes to the creation of wetland habitats to support conservation of native fish species (UCRRP 1988 and 2022, entire); (2) in the Jordan AU, as part of the June sucker recovery implementation program, the USBR and URMCC are restoring, enhancing, and creating wetland habitat conditions along the lower Provo River and Provo River Delta where it connects to Utah Lake (Service 2016, entire). The Provo River Delta restoration project (PRDRP) has already protected Ute ladies'-tresses and was complete in 2024 (Service 2016, entire; US Department of Interior 2024, entire); and (3) in the Snake River AU, as part of the consultation for the operations and maintenance of USBR projects in the Snake River Basin above Brownlee Reservoir, the USBR manages flows to support a more natural hydrograph (USBR 2005b, entire).

Sikes Act and Sikes Act Improvement Act—Federal activities on Department of Defense (DOD) lands are subject to the Sikes Act (Pub. L. 86–797; 16 U.S.C. 670 *et seq.*) and Sikes Act Improvement Act (SAIA; Pub. L. 105–85). The Sikes Act and SAIA provide for cooperation by the DOD, the Department of the Interior (including the Service), and State fish and wildlife agencies in the planning, development, and maintenance of fish and wildlife resources on military installations throughout the United States. Each military department is required to develop and implement an integrated natural resources management plan (INRMP) that must be reviewed on a regular basis, but not less often than every 5 years, and must reflect the agreement of the parties concerning conservation, protection, and management of fish and wildlife resources.

Ute ladies'-tresses was found on the F.E. Warren Air Force Base (FEWAFB) in Wyoming during Colorado butterfly plant (*Gaura neomexicana* var. *coloradensis*) monitoring in August 2023 (Heidel 2023, entire). Given the recent discovery of Ute ladies'-tresses there, the current INRMP does not include protections or conservation measures for Ute ladies'-tresses (INRMP 2022, p. 48). However, the species' habitat is managed under a formal conservation agreement for the Colorado butterfly plant, a plant species delisted under the Act in 2019 (see 84 FR 59570, November 5, 2019), and Preble's meadow jumping mouse (*Zapus hudsonius preblei*), a threatened species under the Act. Management actions include annual monitoring, noxious weed control, avoidance buffers, public access restrictions, riparian habitat protections, and targeted grazing for noxious weed control (FEWAFB 2004, pp. 7–9). These management actions are also beneficial to Ute ladies'-tresses, and we expect them to continue in the future to conserve Preble's meadow jumping mouse and achieve the INRMP's goal of protecting and conserving populations of native plants, fish, and wildlife on FEWAFB.

Federal Power Act—The Federal Power Act (16 U.S.C. 791 *et seq.*) provides for the equal protection of fish and wildlife and other aspects of environmental quality as power and development. As with NEPA, we have the authority to participate in the environmental evaluation process, but acceptance and implementation of our recommendations by a Federal action agency is not required. Under the Federal Power Act, the Federal Energy Regulatory Commission (FERC) is responsible for the regulation of hydropower projects and other interstate energy sources transmission of natural gas, oil, and electricity. In Washington, FERC requires the Chelan Public Utility District (PUD) and Grant PUD to control noxious weeds where Ute ladies'-tresses occurs, conduct regular surveys to document plant numbers and distribution, and conduct a survey of suitable habitats every 5 years to identify new populations (Pope and Cordell 2023, p. 2). The Chelan PUD recently acquired an easement on private land to protect the species and implemented conservation actions to control invasive plants on all landownerships (Pope and Cordell 2023, p. 7). These protections at the Chelan PUD-managed Rocky Reach and Rock Islands occurrences will likely continue, at a minimum, through the post-delisting monitoring period; these protections will continue regardless of the species' listing status under the Act at the Grant PUD-managed Vantage occurrence (LeMoine 2024, entire).

Other Federal Regulatory Mechanisms

We considered the wetland protections from croplands on private lands afforded under the Food Security Act (16 U.S.C. 3801 *et seq.*), but the best available information does not indicate that crops or cropland conversion are stressors to Ute ladies'-tresses.

Various Executive Orders provide guidance for Federal land management agencies to manage for habitat characteristics essential for the conservation of Ute ladies'-tresses. They include Executive Order 11990 (Protection of Wetlands) (May 24, 1977), Executive Order 11988 (Floodplain Management) (May 24, 1977), and Executive Order 13112 (Invasive Species) (February 3, 1999).

State Regulatory Mechanisms

In the United States, Ute ladies'-tresses has State protections in Washington as ''endangered,'' in Nebraska as ''threatened,'' and in Nevada as ''fully protected'' (Washington Natural Heritage Program 2021, pp. 1–2, 104–106; title 163 of the Nebraska Administrative Code at chapter 4, section 163–4–004; and chapter 527 of the Nevada Administrative Code at section 527.010, respectively). In Washington State, the designation of Ute ladies'-tresses as a State endangered plant species prioritizes the conservation of its wetland habitat, and mitigation may be required to offset habitat impacts (Rocchio 2024, entire). In Nebraska, State-listed plant protections generally mirror the Act for endangered and threatened plant species; however, exceptions are provided for normal agricultural practices (title 163 of the Nebraska Administrative Code at chapter 4, section 163–4–004). In Nevada, fully protected species are declared to be threatened with extinction and require a special permit for removal or destruction on public and private lands (chapter 527 of the Nevada Administrative Code at section 527.010, and title 47 of the Nevada Revised Statutes at chapter 527, sections 527.050

and 527.270). There are no State protections for Ute ladies'-tresses in Colorado, Idaho, Montana, Utah, or Wyoming. Ute ladies'-tresses' habitat is protected where it occurs in State wildlife areas in Washington, Idaho, and Utah (Fertig et al. 2005, pp. 72–76; Pope and Cordell 2023, p. 8).

County/City Regulatory Mechanisms

Multiple occurrences (Boulder Creek, South Boulder Creek, and Clear Creek) in the South Platte AU are protected in natural areas and managed by the City of Boulder Open Space and Mountain Parks (OSMP) to conserve rare or endangered plant species and their habitats (see title 33 of the Colorado Revised Statutes at section 33–33–104). The City of Boulder's OSMP manages open space in perpetuity to preserve natural areas, water resources, floodplains, and wildlife habitats (Riedel 2004, p. 1; City of Boulder OSMP 2024, p. 4). Most of the Ute ladies'-tresses plants in Boulder County are protected in the South Boulder Creek State Natural Area and Tallgrass Natural Area, which include approximately 1,347 ac (545 ha) of remnant tallgrass prairie habitat (Riedel 2002, pp. 1, 7; City of Boulder OSMP 2023, entire). Boulder's OSMP would likely continue to protect Ute ladies'-tresses if Federal protections are removed (Riedel 2024, pers. comm.). Additionally, the title 9 of the City of Boulder's Municipal Code at section 9–3–9 (Stream, Wetlands, and Water Body Protection) ensures the preservation, protection, restoration, and enhancement of the quality and diversity of wetlands and water bodies; this city regulation would continue to protect Ute ladies'-tresses habitat if the species is delisted under the Act.

Private Lands

Conservation efforts that have been performed by private entities to benefit and conserve Ute ladies'-tresses are discussed here.

In the Lower Bear AU, the single occurrence, Mendon Meadows, is protected as a preserve specifically for Ute ladies'-tresses, and the land is managed solely for the species (Bear River Land Trust (BRLT) 2014, entire). Management practices include regular surveys, irrigation, seasonal grazing or mowing that avoids the flowering period, a prohibition on recreation and development, and restrictions on herbicide use (BRLT 2014, pp. 6, 14, 16). Long-term habitat protections are provided for this Ute ladies'-tresses occurrence, and if we delist the species, any future changes would need Service approval (BRLT 2014, pp. 3, 5–6).

Tribal Lands

Occurrences in the Lower Green River, Upper Snake, and Upper Columbia AUs occur on Tribal lands (Fertig et al. 2005, pp. 71, 74, 77–78; Service 2024, pp. 39, 51, 69, 75). We are not aware of regulations that provide protections to Ute ladies'-tresses on Tribal lands.

Overall, the conservation measures and regulatory mechanisms afforded to wetland riparian habitats on Federal, State, and private lands in the United States and on British Columbia Parks and Federal Crown lands in Canada minimize the effects of anthropogenic stressors to Ute ladies'-tresses, in particular the threat of urban development to the species' habitat, regardless of the species' status under the Act.

Proposed Determination of Ute Ladies'-Tresses' Status

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species meets the definition of an endangered species or a threatened species. The Act defines an ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range, and a ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether a species meets the definition of an endangered species or a threatened species because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.

When we listed Ute ladies'-tresses as threatened in 1992 (see 57 FR 2048; January 17, 1992), we identified habitat loss and modification due to water development and urbanization (Factor A) as the primary threat to the species. We considered collection (Factor B) to be a threat because it is an orchid species. Disease and predation (Factor C) were not considered threats. Regulatory mechanisms (Factor D) included a limited degree of protection for the species' wetland habitat under the Clean Water Act and for the species itself through the regulation of international trade for all orchids by CITES. Finally, we identified small and scattered populations, the variable demographic structure of populations, and a presumed slow reproductive rate (Factor E) as vulnerabilities to threats and stressors. In our SSA report, we evaluated these stressors and additional stressors that were identified after the time of listing. Much more is presently known about the species and its stressors than at the time of listing. The best available information indicates that habitat loss from anthropogenic activities (Factor A) and climate change (Factor E) are the most influential threats affecting Ute ladies'-tresses now and into the future, although we acknowledge there is uncertainty about the future impacts of anthropogenic activities and climate change to the species and its habitats.

We consider the severity and magnitude of the primary threat, habitat loss and modification due to urbanization and water development (we refer to this threat as water management here and in the SSA report) (Factor A) to be much lower now than we believed at the time of listing, given the increase in the number of known Ute ladies'-tresses populations and the increase in the extent of the species' known range based on new information over the past 32 years. While this threat has resulted in the localized loss of occurrences and the extirpation of one historical AU (Upper Arkansas), it does not result in a species-level impact given the much larger number of known occurrences, AUs, and species' range that comprise the species' current status. Future projections of this threat in combination with other anthropogenic stressors indicate that this threat will increase in the future, but will remain localized within the species' range and will be minimized by conservation measures and regulatory mechanisms afforded to wetland riparian habitats on Federal, State, and private lands in the United States and on British Columbia Parks and Federal Crown lands in Canada regardless of Ute ladies'-tresses' status under the Act (see *Conservation Efforts and Regulatory Mechanisms,* above).

Collection (Factor B) from the wild has not occurred at the level anticipated at the time of listing presumably because the species is less showy than the tropical orchids and other *Spiranthes* species available for purchase (see ''Collection,'' above). Protections from collection and international trade are also afforded by CITES for all orchids; these protections are not contingent on an orchid species being federally listed. Disease and

predation (Factor C) have not materialized since listing.

Climate change (Factor E) and drought (Factor A) are not currently having a population-level or species-level effect on Ute ladies'-tresses and are not projected to result in a species-level effect in the future. The best available information indicates that these stressors have not resulted in the extirpation of occurrences or AUs. Future projections of climate change indicate that the frequency of severe and extreme droughts may decrease or remain the same in some areas of the range, but in much of the range, the frequency will increase above current trends. Ute ladies'-tresses is drought-tolerant and adapted to a range of soil moisture conditions, which increases its resilience to potential future increases in severe and extreme drought frequency. The resiliency of Ute ladies'-tresses AUs varies across the species' range. Ute ladies'-tresses AUs along large, mainstem rivers with multiple occurrences (Upper Green, Lower Green River, Upper Columbia, Upper Snake, Lower Bear, Niobrara, Colorado Headwaters) are the most resilient; they maintain their overall resiliency scores across all future scenarios despite projected declines in abundance and connectivity. The Upper Colorado-Dirty Devil AU in the southern part of the range is the least resilient and is projected to be extirpated in all three future scenarios due to climate change. Based on the best available information, the majority of AUs are tolerant of the effects of climate change (Factor E) and are able to withstand the cumulative effects of all stressors (Factor E).

We also evaluated a variety of conservation efforts and regulatory mechanisms (Factor D) that either reduce or ameliorate stressors and improve or maintain habitat conditions and population resiliency in the absence of the Act's protections. The Clean Water Act provides some habitat protections for Ute ladies'-tresses occurrences in jurisdictional waters/wetlands, such along interstate waters or along intrastate lakes, ponds, streams, and wetlands that are relatively permanent, standing or continuously flowing bodies of water with a continuous surface connection to certain waterbodies. Habitat protections for wetland and riparian habitats are also afforded to the species on Federal lands by regulatory mechanisms provided by the NPS Organic Act on NPS lands in Colorado and Utah; the National Wildlife Refuge System Improvement Act on Service refuge lands in Colorado; the National Forest Management Act of 1976 and USFS National Forest plans on USFS lands in Utah and Idaho; the Federal Land Policy and Management Act and BLM RMPs and ACEC designations on BLM lands in Colorado, Utah, Idaho, Washington, and Wyoming; and the Sikes Act and Sikes Act Improvement Act and INRMPs on DOD lands in Wyoming (see *Conservation Efforts and Regulatory Mechanisms,* above). The USBR and FERC regulate the hydrological regime and, in doing so, provide some habitat protection along rivers and streams in some watersheds for the benefit of federally listed fish species and other resources, which indirectly benefits Ute ladies'-tresses.

In Canada, Ute ladies'-tresses is protected within an Ecological Reserve managed by British Columbia Parks as well as on Federal Crown land as a schedule 1 endangered species under SARA. Ute ladies'-tresses also receives partial protections on State lands in Washington, Nevada, and Nebraska and on open space lands in Boulder County, Colorado. Due in part to the regulatory mechanisms described here on Federal lands and other protected lands, the anthropogenic threats to the species, particularly the threat of urban development to the habitat of Ute ladies'-tresses, have been sufficiently reduced.

Status Throughout All of Its Range

Endangered Throughout Its Range Determination

Our evaluation of the current condition of Ute ladies'-tresses found that there are currently 18 AUs distributed across eight U.S. States and one Canadian Province. Ute ladies'-tresses' current condition represents a marked improvement from what we understood its condition to be when we first listed it as a threatened species in 1992. Over the last three decades, many more occurrences have been discovered in an additional 14 AUs, increasing both numbers and the species' known geographic range. Thirteen AUs have high or moderate resilience to stochastic events, and these AUs are distributed across 6 U.S. States and Canada. The high or moderately resilient AUs typically display a combination of resilient habitat (based on vegetative habitat condition and hydrologic condition) and demographic factors (based on the number of occurrences, connectivity within the AU, and potentially suitable habitat within the AU) that enable them to adequately withstand environmental and demographic stochasticity. The five AUs with low resiliency are less able to withstand stochastic events.

While some stressors have impacted occurrences and AUs, none are having species-level impacts individually or cumulatively. The severity and magnitude of the primary threat, habitat loss and modification due to urbanization and water development, is much lower now than believed at the time of listing; it has resulted in the extirpation of localized occurrences across the range, including one historical AU (Upper Arkansas), representing 5 percent of the species' 19 historical AUs, and some of the occurrences in three extant AUs (South Platte, Jordan, and Weber) in Colorado and Utah (see ''Urban Development,'' above). Despite these impacts, the South Platte and Jordan AUs remain in moderate and high current condition, respectively (see table 1, above). Ute ladies'-tresses is tolerant of and adapted to the altered habitat conditions in AUs from various stressors, as well drought and climate change and the cumulative effects of all stressors.

With 18 AUs distributed across 12 ecoregions and 7 habitat types, the species currently has sufficient resiliency, redundancy, and representation to withstand stochastic and catastrophic events and adapt to changes. Therefore, we find that Ute ladies'-tresses is not in danger of extinction throughout all of its range.

Threatened Throughout Its Range Determination

Under the Act, a threatened species is any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range (16 U.S.C. 1532(20)). The foreseeable future extends only so far into the future as the Service can make reasonably reliable predictions about the threats to the species and the species' responses to those threats (50 CFR 424.11(d)). The Service describes 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 (50 CFR 424.11(d)). The key statutory difference between a threatened species and an endangered species is the timing of when a species may be in danger of extinction, either now (endangered species) or in the foreseeable future (threatened species).

For the purposes of our analysis, we defined the foreseeable future for Ute ladies'-tresses as approximately 50 years (to 2074). We relied on combined climate and land use projections by the IPCC out to 2074, the timeframe for which they were available. These

projections provide the best available evaluation of the primary stressors to the species. After 2074, we do not have information that reliably projects the combined effects of climate change and habitat loss from anthropogenic activities within the species' range. We also selected this timeframe because it allows us to reliably project changes in other species' stressors and land management and is biologically meaningful to the species to begin to understand the response of ecosystems to those changes. By 2074, we anticipate a range of plausible future conditions for Ute ladies'-tresses.

Our evaluation of the projected future condition of Ute ladies'-tresses found that resiliency and redundancy are projected to decline under all three plausible future scenarios based on the future impacts of anthropogenic activities and climate change. In general, the species' range is projected to become hotter and drier under all three future scenarios, even under the most optimistic scenario (Scenario 1). Declines in resiliency and redundancy were driven by climate change in Scenario 1 and the combination of anthropogenic activities and climate change in Scenarios 2 and 3. Despite the combined effects of anthropogenic activities and climate change, Ute ladies'-tresses' life-history characteristics (such as its capability for extended, underground dormancy during unfavorable conditions including drought and habitat changes (*e.g.,* vegetative succession); its dispersal and colonization ability within watersheds to escape land use and habitat changes; and its ability to thrive in human-managed water systems that have altered flow regimes) confer sufficient resiliency to the projected hotter, drier hydrological conditions, as well as habitat and land use changes.

The plausible future condition of Ute ladies'-tresses in 2074 ranges from 17 AUs across the range with 13 of those AUs being highly or moderately resilient to stochastic events (Scenario 1) to 16 AUs across the range with 10 of those AUs being highly or moderately resilient (Scenario 3). While the species' actual future condition may fall anywhere between Scenarios 1 and 3, even if we assume that Scenario 3 (the worst-case) were to occur, the species is projected to maintain 16 AUs across its range, with 11 of those AUs projected to maintain the same condition as their current condition. Ten of the 16 AUs in 6 States (Colorado, Idaho, Nebraska, Utah, Wyoming, and Washington) and Canada are projected to be highly or moderately resilient to stochastic events. Ute ladies'-tresses' redundancy declines slightly from 18 AUs to 16 AUs, with a contraction along the southern part of its current range due to projected extirpations in Nevada (Lower Colorado-Lake Mead AU) and southern Utah (Upper Colorado-Dirty Devil AU). Representation is projected to be similar to current conditions, as the species is projected to maintain the same number of ecoregions (12) and habitat types (7) across its range. Therefore, even in the worst-case scenario, our analysis suggests that losses of resiliency and redundancy would be modest, with 16 AUs remaining across the range, and 10 of those AUs remaining in moderate or high condition, with no major changes in representation expected. Collectively, this suggests that in 50 years, viability of the species will not be significantly reduced (Service 2024, pp. 198–199). Recovery efforts, particularly survey efforts that have identified many more occurrences, have increased Ute ladies'-tresses' known resiliency, redundancy, and representation such that the species is now better able to recover from impacts noted at the time of listing, and we anticipate that Ute ladies'-tresses will retain sufficient levels of resiliency, redundancy, and representation in the foreseeable future.

Two factors support the maintenance of the current condition in 11 AUs and the moderate to high future resiliency of at least 10 AUs: (1) regulatory mechanisms and conservation efforts, and (2) the species' biological characteristics. First, the maintenance of the current condition and the high to moderate resiliency of more than half of Ute ladies'-tresses AUs is, in part, due to habitat protections and regulations implemented by Canada; U.S. Federal agencies; the States of Washington, Nebraska, and Nevada; the City of Boulder; and private entities (Factor D) that will continue to be implemented into the future, even in the absence of protections afforded by the Act, as described above under *Conservation Efforts and Regulatory Mechanisms.* These protections will continue to limit the potential effects of stressors on Ute ladies'-tresses in the future.

Second, independent of future regulatory mechanisms and conservation efforts, Ute ladies'-tresses' biological characteristics moderate its response to increasing stressors. Ute ladies'-tresses' ruderal life-history strategy; adaptation and resilience to disturbance (stochastic events) such as flooding, mowing, and grazing; its dispersal and colonization ability in many habitat types; and its drought tolerance all increase its resilience to potential future increases in stressors and habitat and environmental changes (representation) evidenced by the species' past ability to maintain high and moderate resiliency in the face of ongoing stressors in the Jordan and South Platte AUs. Although habitat conditions could become considerably drier under Scenario 3, Ute ladies'-tresses is hardy and already adapted to periods of drought. Individuals may live many decades and have maintained healthy recruitment and survival despite drought conditions and other climatic variation in the past.

We recognize that some habitat-related threats remain present, and they have ongoing impacts to Ute ladies'-tresses AUs. We acknowledge that the specific effects of climate change on Ute ladies'-tresses and its habitat are uncertain and may have a negative impact. However, we found that current and expected patterns in site protection and habitat management (Factor D) and the species' adaptation and resilience to disturbance are sufficient to prevent effects at the species level.

After evaluating threats to the species and assessing the cumulative effect of the threats under the Act's section 4(a)(1) factors, and considering the levels of resiliency, redundancy, and representation projected under the current and future scenarios described in the SSA report, Ute ladies'-tresses will be able to withstand stochastic events, catastrophic events, and environmental change now and into the foreseeable future. Thus, after assessing the best available information, we conclude that Ute ladies'-tresses is not in danger of extinction now or likely to become so within the foreseeable future throughout all of its range.

Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so within the foreseeable future throughout all or a significant portion of its range. Having determined that Ute ladies'-tresses is not in danger of extinction or likely to become so within the foreseeable future throughout all of its range, we now consider whether it may be in danger of extinction (*i.e.,* endangered) or likely to become so within the foreseeable future (*i.e.,* threatened) in a significant portion of its range—that is, whether there is any portion of the species' range for which both (1) the portion is significant; and (2) the species is in danger of extinction or likely to become so within the foreseeable future in that portion. Depending on the case, it might be more efficient for us to address the ''significance'' question or the ''status''

question first. We can choose to address either question first. Regardless of which question we address first, if we reach a negative answer with respect to the first question that we address, we do not need to evaluate the other question for that portion of the species' range.

In undertaking this analysis for Ute ladies'-tresses, we choose to address the status question first. We began by identifying portions of the range where the biological status of the species may be different from its biological status elsewhere in its range. For this purpose, we considered information pertaining to the geographic distribution of (a) occurrences of the species, (b) the threats that the species faces, and (c) the resiliency condition of AUs (populations).

We evaluated the range of Ute ladies'-tresses to determine if the species is in danger of extinction now or likely to become so within the foreseeable future in any portion of its range. The range of a species can theoretically be divided into portions in an infinite number of ways. We focused our analysis on portions of the species' range that may meet the Act's definition of an endangered species or a threatened species. For Ute ladies'-tresses, we considered whether the threats or their effects on the species are greater in any biologically meaningful portion of the species' range than in other portions such that the species is in danger of extinction now or likely to become so within the foreseeable future in that portion. We examined the following threats: anthropogenic activities including urban development, water management, agriculture, livestock grazing, recreation, invasive plants, and collection; and environmental conditions including vegetative succession, disease or predation, drought, climate change, and human population change, including cumulative effects.

We examined the range of Ute ladies'-tresses for biologically meaningful portions that may be at a higher risk of extirpation, as reflected by potentially larger climate change effects and anthropogenic effects to the species. We determined that by itself, any single AU is too small to be considered a biologically meaningful portion of the range for Ute ladies'-tresses because each AU represents a small percentage (6 percent) of the total number of the 18 AUs rangewide, and each AU contains only a small area of the species' range. Therefore, even though the Upper Columbia AU is separate from the rest of the range, we do not consider it to be a biologically meaningful portion on its own.

We identified seven AUs that are a geographically concentrated grouping at a biologically meaningful scale along the southern edge of Ute ladies'-tresses' overall range; those seven AUs are the Great Salt Lake, Jordan, Lower Colorado-Lake Mead, Upper Colorado-Dirty Devil, Lower Green River, Colorado Headwaters, and South Platte AUs. Relative to the remainder of the range, this portion of the range is impacted by elevated levels of drought, climate change, and anthropogenic stressors now and into the future.

This portion may be at higher risk of extirpation, as reflected by the current and future resiliency of the seven AUs. Currently, three of these seven AUs have low resiliency, so they are at a greater risk of extirpation than the other four AUs, two of which have high resiliency and two have moderate resiliency. We examined the following threats, for the reasons described above: anthropogenic activities including urban development, water management, agriculture, livestock grazing, recreation, invasive plants, and collection; and environmental conditions including vegetative succession, disease or predation, drought, climate change, and human population change, including cumulative effects. We concluded that although almost half of the AUs in this portion have low resiliency, the species has sufficient resiliency, redundancy, and representation across the seven AUs in the portion. The three AUs in low condition (Great Salt Lake, Lower Colorado-Lake Mead, Upper Colorado-Dirty Devil) have sufficiently high or moderate hydrologic condition to remain viable in the near term despite lower scores for other metrics such as AU abundance and connectivity. The seven AUs cover a wide geographic area that spans portions of four States across a variety of climatic and habitat types from north-to-south and east-to-west, such that there is no stochastic or catastrophic event that would extirpate the portion in the near term. Therefore, we conclude that the risk of extinction in the portion is not low now, and the species in this portion does not meet the Act's definition of an endangered species.

We also evaluated the status of this portion into the foreseeable future. In the future, three of the seven AUs are projected to have low resiliency or be extirpated (Great Salt Lake, Upper Colorado-Dirty Devil, Lower Colorado-Lake Mead), one AU may have moderate to low resiliency (South Platte), and the other three AUs have moderate to high resiliency (Jordan, Lower Green River, Colorado Headwaters). We examined the same threats described above for the species: anthropogenic activities including urban development, water management, agriculture, livestock grazing, recreation, invasive plants, collection; and environmental conditions including vegetative succession, disease or predation, drought, climate change, human population change, including cumulative effects. We concluded that although two AUs in this portion may be extirpated, the species has sufficient resiliency, redundancy, and representation in the remaining five AUs in the portion. The one AU consistently in low condition (Great Salt Lake) is projected to maintain sufficiently moderate hydrologic and vegetative condition to remain viable into the foreseeable future despite lower scores for other metrics such as AU abundance and connectivity. The five AUs cover a wide geographic area that spans portions of three States across a variety of climatic and habitat types from north-to-south and east-to-west, such that there is no stochastic or catastrophic event that would extirpate the portion in the foreseeable future. Even with two AUs in low condition and the slight increase in extinction risk under Scenario 3, we found that the current and projected patterns of habitat management and protection, the hydrologic condition of the AUs, and the species' adaptation to disturbance are sufficient to prevent effects to the species that would cause it to meet the Act's definition of an endangered species or a threatened species. Therefore, we conclude that the risk of extinction in the portion is low in the foreseeable future and the species in this portion does not meet the Act's definition of a threatened species.

As a result, we found no portion of Ute ladies'-tresses' range where the biological condition of the species differs from its condition elsewhere in its range such that the status of the species in that portion differs from any other portion of the species' range. Therefore, the portion both currently and into the future has enough resiliency such that it is not at risk of extinction now or within the foreseeable future. Because we determined that this portion does not have a different status, we did not need to assess its potential significance.

Therefore, we find that the species is not in danger of extinction now or likely to become so within the foreseeable future in any significant portion of its range. This does not conflict with the courts' holdings in *Desert Survivors* v. *Department of the Interior,* 336 F. Supp. 3d 1131 (N.D. Cal. 2018), and *Center for*

Biological Diversity v. *Jewell,* 248 F. Supp. 3d. 946, 959 (D. Ariz. 2017) because, in reaching this conclusion, we did not apply the aspects of the Final Policy on Interpretation of the Phrase ''Significant Portion of Its Range'' in the Endangered Species Act's Definitions of ''Endangered Species'' and ''Threatened Species'' (79 FR 37578; July 1, 2014), including the definition of ''significant'' that those court decisions held to be invalid.

Determination of Status

Our review of the best available scientific and commercial information indicates that Ute ladies'-tresses does not meet the Act's definition of endangered species or threatened species in accordance with sections 3(6) and 3(20) of the Act. In accordance with our current regulations at 50 CFR 424.11(e)(2), Ute ladies'-tresses has recovered and no longer warrants listing. Therefore, we propose to remove Ute ladies'-tresses from the Federal List of Endangered and Threatened Plants.

Effects of This Rule

This proposed rule, if made final, would revise 50 CFR 17.12(h) by removing Ute ladies'-tresses from the Federal List of Endangered and Threatened Plants. The prohibitions and conservation measures provided by the Act, particularly through sections 7 and 9, would no longer apply to this species. Federal agencies would no longer be required to consult with the Service under section 7 of the Act if activities they authorize, fund, or carry out may affect Ute ladies'-tresses.

There is no critical habitat designated for this species, so there would be no effect to 50 CFR 17.96.

Post-Delisting Monitoring

Section 4(g)(1) of the Act requires us, in cooperation with the States, to implement a monitoring program for not less than 5 years for all species that have been recovered. Post-delisting monitoring (PDM) refers to activities undertaken to verify that a species delisted due to recovery remains secure from the risk of extinction after the protections of the Act no longer apply. The primary goal of PDM is to monitor the species to ensure that its status does not deteriorate, and if a decline is detected, to take measures to halt the decline so that proposing it as endangered or threatened is not again needed. If, at any time during the monitoring period, data indicate that protective status under the Act should be reinstated, we can initiate listing procedures, including, if appropriate, emergency listing.

We have prepared a draft PDM plan for Ute ladies'-tresses. The draft PDM plan: (1) summarizes the status of Ute ladies'-tresses at the time of proposed delisting; (2) describes the frequency and duration of monitoring; (3) discusses monitoring methods and potential sampling regimes; (4) defines what potential triggers will be evaluated to address the need for additional monitoring; (5) outlines reporting requirements and procedures; (6) proposes a schedule for implementing the PDM plan; and (7) defines responsibilities. It is our intent to work with our partners towards maintaining the recovered status of Ute ladies'-tresses. We appreciate any information on what should be included in post-delisting monitoring strategies for this species (see Information Requested, above).

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with federally recognized Tribes on a government-to-government basis. In accordance with Secretary's Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. We notified and invited the following Tribes to participate in the SSA process and to provide information at the beginning of the SSA process: Shoshone-Bannock Tribes, Eastern Shoshone Tribe, Confederated Salish and Kootenai Tribes, Blackfeet Nation, Ute Tribe of the Uintah and Ouray Reservation, Confederated Tribes of the Colville Reservation, and Confederated Tribes and Bands of the Yakama Nation. We did not receive a response from any Tribe. We will continue to work with Tribal entities during the development of a final delisting determination for Ute ladies'-tresses.

References Cited

A complete list of references cited in this rulemaking is available on the internet at *https://www.regulations.gov* and upon request from the Utah Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Fish and Wildlife Service's Species Assessment Team and the Utah Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

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

Signing Authority

Martha Williams, Director of the U.S. Fish and Wildlife Service, approved this action on November 18, 2024. Acting Director Steve Guertin approved these packages December 15, 2024. On December 16, 2024, the acting Director authorized the undersigned to sign the document electronically and submit it to the Office of the Federal Register for publication as an official document of the U.S. Fish and Wildlife Service.

Proposed Regulation Promulgation

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

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

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

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

§ 17.12 [Amended]

■ 2. In 17.12, in paragraph (h), amend the List of Endangered and Threatened Plants by removing the entry for ''*Spiranthes diluvialis*'' under FLOWERING PLANTS.

Madonna Baucum,

Regulations and Policy Chief, Division of Policy, Economics, Risk Management, and Analytics of the Joint Administrative Operations, U.S. Fish and Wildlife Service.

[FR Doc. 2024–30380 Filed 1–6–25; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register
Vol. 90, No. 4
Tuesday, January 7, 2025

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–869]

Diffusion-Annealed, Nickel-Plated Flat-Rolled Steel Products From Japan: Final Results of Expedited Second Sunset Review of Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of this expedited sunset review, the U.S. Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) order on diffusion-annealed, nickel-plated flat-rolled steel products (nickel-plated steel products) from Japan would be likely to lead to the continuation or recurrence of dumping at the dumping margins identified in the ''Final Results of Review'' section of this notice.

DATES: Applicable January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Robert Copyak, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3642.

SUPPLEMENTARY INFORMATION:

Background

On September 3, 2024, Commerce published the notice of initiation of the second sunset reviews of the *Order,*[1] pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On September 18, 2024, Commerce received a notice of intent to participate from Thomas Steel Strip Corporation (Thomas Steel), a domestic interested party, within the 15-day period specified in 19 CFR 351.218(d)(1)(i).[3] Thomas Steel claimed interested party status under section 771(9)(C) of the Act, as a producer of the domestic like product in the United States.

On October 3, 2024, Thomas Steel filed an adequate substantive response within the deadline specified in 19 CFR 351.218(d)(3)(i).[4] Commerce did not receive a substantive response from any respondent interested party. On October 31, 2024, Commerce notified the U.S. International Trade Commission (ITC) that it did not receive an adequate substantive response from respondent interested parties.[5] As a result, pursuant to section 751(c)(3)(A) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited (120-day) sunset review of the *Order*.

Scope of the Order

The merchandise covered by the *Order* is nickel-plated steel products from Japan. For a complete description of the scope of the *Order, see* the Issues and Decision Memorandum.[6]

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review, including the likelihood of the continuation or recurrence of dumping and the magnitude of the margins likely to prevail if the *Order* was to be revoked, is provided in the Issues and Decision Memorandum. A list of the topics discussed in the Issues and Decision Memorandum is included as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed at *http://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Sunset Review

Pursuant to sections 751(c)(1), and 752(c)(1) and (3) of the Act, Commerce determines that revocation of the *Order* would be likely to lead to the continuation or recurrence of dumping. We determine that the weighted-average dumping margin likely to prevail would be up to 77.70 percent.[7]

Administrative Protective Order (APO)

This notice serves as the only reminder to parties subject to APO of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these final results in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, and 19 CFR 351.221(c)(5)(ii).

Dated: December 30, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. History of the *Order*
V. Legal Framework
VI. Discussion of the Issues
  1. Likelihood of Continuation or Recurrence of Dumping
  2. Magnitude of the Margins of Dumping Likely to Prevail
VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2025–00019 Filed 1–6–25; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Diffusion-Annealed, Nickel-Plated Flat-Rolled Steel Products from Japan: Antidumping Duty Order,* 79 FR 30816 (May 29, 2014) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 89 FR 71252 (September 3, 2024).

[3] *See* Thomas Steel's Letter, ''Notice of Intent to Participate,'' dated September 18, 2024.

[4] *See* Thomas Steel's Letter, ''Substantive Response to Notice of Initiation of Five-Year (Sunset) Reviews of the Antidumping Duty Order,'' dated October 3, 2024.

[5] *See* Commerce's Letter, ''Sunset Reviews Initiated on September 3, 2024,'' dated October 31, 2024.

[6] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited Second Sunset Review of the Antidumping Duty Order on Diffusion-Annealed, Nickel-Plated Flat-Rolled Steel Products from Japan'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[7] *Id.* at 3.

DEPARTMENT OF COMMERCE

International Trade Administration

Environmental Technologies Trade Advisory Committee

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an open meeting of a Federal Advisory Committee.

SUMMARY: The Environmental Technologies Trade Advisory Committee (ETTAC) will hold an in-person meeting on Tuesday, January 28, 2025 at the U.S. Department of Commerce in Washington, DC. The meeting is open to the public with registration instructions provided below. This notice sets forth the schedule and proposed topics for the meeting.

DATES: The meeting is scheduled for Tuesday, January 28, 2025 from 9:00 a.m. to 5:00 p.m. Eastern Time (ET). The deadline for members of the public to register to participate, including requests to make comments during the meeting and for auxiliary aids, or to submit written comments for dissemination prior to the meeting, is 5:00 p.m. EST on Wednesday, January 22, 2025. Members of the public must register by that date to participate.

ADDRESSES: The meeting will be held in-person in the Commerce Research Library at the U.S. Department of Commerce Herbert Clark Hoover Building, 1401 Constitution Avenue NW, Washington, DC 20230. Requests to register to participate (including to speak or for auxiliary aids) and any written comments should be submitted via email to Ms. Megan Hyndman, Office of Energy & Environmental Industries, International Trade Administration, at *Megan.Hyndman@trade.gov.* This meeting has a limited number of spaces for members of the public to attend in-person. Requests to participate in-person will be considered on a first-come, first-served basis.

FOR FURTHER INFORMATION CONTACT: Ms. Megan Hyndman, Office of Energy & Environmental Industries, International Trade Administration (Phone: 202–823–1839; email: *Megan.Hyndman@trade.gov*).

SUPPLEMENTARY INFORMATION: The ETTAC is mandated by Section 2313(c) of the Export Enhancement Act of 1988, as amended, 15 U.S.C. 4728(c), to advise the Environmental Trade Promotion Working Group of the Trade Promotion Coordinating Committee, through the Secretary of Commerce, on the development and administration of programs to expand U.S. exports of environmental technologies, goods, services, and products. The ETTAC was most recently re-chartered through August 12, 2026.

On Tuesday, January 28, 2025 from 9:00 a.m. to 5:00 p.m. ET, the ETTAC will hold the first meeting of its current charter term. During the meeting, committee members will deliberate on priority topics to address during the 2024–2026 ETTAC charter and determine subcommittee topics and ETTAC leadership. An agenda will be made available one week prior to the meeting upon request to Megan Hyndman.

The meeting will be open to the public and time will be permitted for public comment before the close of the meeting. Members of the public seeking to attend the meeting are required to register by Wednesday, January 22, at 5:00 p.m. EST, via the contact information provided above. This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to OEEI at *Megan.Hyndman@trade.gov* or (202) 823–1839 no less than one week prior to the meeting. Requests received after this date will be accepted, but it may not be possible to accommodate them.

Written comments concerning ETTAC affairs are welcome any time before or after the meeting. To be considered during the meeting, written comments must be received by Wednesday, January 22, 2025, at 5:00 p.m. EST to ensure transmission to the members before the meeting. Draft minutes will be available within 30 days of this meeting.

Dated: December 31, 2024.

Man K. Cho,

Deputy Director, Office of Energy and Environmental Industries.

[FR Doc. 2025–00076 Filed 1–6–25; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–803, A–570–928, A–791–821]

Uncovered Innerspring Units From the People's Republic of China, the Socialist Republic of Vietnam, and South Africa: Final Results of the Expedited Third Sunset Reviews of the Antidumping Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of these expedited sunset reviews, the U.S. Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) orders on uncovered innerspring units (innersprings) from the People's Republic of China (China), the Socialist Republic of Vietnam (Vietnam), and South Africa would be likely to lead to the continuation or recurrence of dumping at the levels indicated in the ''Final Results of Sunset Reviews'' section of this notice.

DATES: Applicable January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Christopher Maciuba, 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.

SUPPLEMENTARY INFORMATION:

Background

On December 11, 2008, Commerce published the AD orders on innersprings from South Africa and Vietnam and, on February 19, 2009, Commerce published the AD order on innersprings from China in the **Federal Register**.[1] On September 3, 2024, Commerce published the notice of initiation of the third sunset reviews of the *Orders,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2]

On September 10, 2024, Commerce received notices of intent to participate in these sunset reviews from Leggett and Platt Incorporated (Leggett) within the deadline specified in 19 CFR 351.218(d)(1)(i).[3] Leggett claimed domestic interested party status under section 771(9)(C) of the Act as a producer of the domestic like product in the United States. On October 3, 2024, Commerce received adequate substantive responses from Leggett within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] We received

[1] *See Antidumping Duty Order: Uncovered Innerspring Units from South Africa,* 73 FR 75390 (December 11, 2008); *Antidumping Duty Order: Uncovered Innerspring Units from the Socialist Republic of Vietnam,* 73 FR 75391 (December 11, 2008); and *Uncovered Innerspring Units from the People's Republic of China: Notice of Antidumping Duty Order,* 74 FR 7661 (February 19, 2009) (collectively, the *Orders*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 89 FR 71252 (September 3, 2024).

[3] *See* Leggett's Letters, ''Uncovered Innersprings from China: Notice of Intent to Participate,'' dated September 10, 2024; ''Uncovered Innersprings from South Africa: Notice of Intent to Participate,'' dated September 10, 2024; and ''Uncovered Innersprings from Vietnam: Notice of Intent to Participate,'' dated September 10, 2024.

[4] *See* Leggett's Letters, ''Uncovered Innersprings from Vietnam: Substantive Response,'' dated

no substantive responses from respondent interested parties.

On October 31, 2024, Commerce notified the U.S. International Trade Commission that it did not receive substantive responses from respondent interested parties.[5] Pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce is conducting expedited (120-day) sunset reviews of the *Orders.*

Scope of the Orders

The products covered by the *Orders* are innersprings from China, South Africa, and Vietnam. For a full description of the scope of the *Orders, see* the Issues and Decision Memorandum.[6]

Analysis of Comments Received

A complete discussion of all issues raised in these sunset reviews is contained in the Issues and Decision Memorandum.[7] A list of topics discussed in the Issues and Decision Memorandum is included as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be directly accessed at *http://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Sunset Reviews

Pursuant to sections 751(c)(1), and 752(c)(1) and (3) of the Act, Commerce determines that revocation of the *Orders* would likely lead to the continuation or recurrence of dumping and that the magnitude of the dumping margins likely to prevail would be weighted-average dumping margins up to 234.51 percent for China, 121.39 percent for South Africa, and 116.31 percent for Vietnam.[8]

October 3, 2024; ''Uncovered Innersprings from China: Substantive Response,'' dated October 3, 2024; and ''Uncovered Innersprings from South Africa: Substantive Response,'' dated October 3, 2024.

[5] *See* Commerce's Letter, ''Sunset Reviews Initiated on September 3, 2024,'' dated October 31, 2024.

[6] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited Third Sunset Reviews of the Antidumping Duty Orders on Uncovered Innerspring Units from the People's Republic of China, the Socialist Republic of Vietnam, and South Africa,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum) at 2–3.

[7] *Id.*

[8] *Id.* at 12.

Administrative Protective Order (APO)

This notice serves as the only reminder to interested parties subject to an APO of their responsibility concerning the return/destruction or conversion to judicial protective order of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, and 19 CFR 351.218(e)(1)(ii)(C)(2) and 351.221(c)(5)(ii).

Dated: December 31, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Orders*
IV. History of the *Orders*
V. Legal Framework
VI. Discussion of the Issues
  1. Likelihood of Continuation or Recurrence of Dumping
  2. Magnitude of the Margins of Dumping Likely to Prevail
VII. Final Results of Sunset Reviews
VIII. Recommendation

[FR Doc. 2025–00016 Filed 1–6–25; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Establishing an Advisory Council Pursuant to the National Marine Sanctuaries Act and Solicitation for Applications for the Chumash Heritage National Marine Sanctuary Advisory Council

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service, National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Notice of solicitation.

SUMMARY: Notice is hereby given that NOAA is establishing a national marine sanctuary advisory council for the Chumash Heritage National Marine Sanctuary (CHNMS), the designation of which became effective on November 30, 2024. The council will provide guidance to ONMS and will serve as liaisons with constituents and community groups. As a result, ONMS is adding the new council to the list of established national marine sanctuary advisory councils. ONMS solicits applications to fill council seats on an as needed basis and is seeking applicants for seats on the CHNMS Advisory Council. This notice contains web page links and contact information for CHNMS and application materials to apply for the newly established advisory council.

DATES: Applications for membership on the CHNMS Advisory Council need to be postmarked or received by Friday March 7, 2025.

ADDRESSES: For further information contact: Nicole Capps, NOAA ONMS West Coast Region Program Analyst, 99 Pacific Street, Building 100F, Monterey, CA 93940; 831–647–6451; *nicole.capps@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 315 of the National Marine Sanctuaries Act (NMSA) (16 U.S.C. 1445a) authorizes the Secretary of Commerce to establish advisory councils to advise and make recommendations regarding the designation and management of national marine sanctuaries. ONMS is establishing a new sanctuary advisory council for CHNMS to serve as a liaison with the local community and to provide guidance and advice to ONMS regarding the sanctuary management plan. The advisory council for CHNMS was not established when ONMS published its annual announcement on May 24, 2024 that was advertising to fill vacant seats on the other 18 councils (89 FR 45854). Therefore, ONMS is adding the new advisory council to the list of sites with open vacancies and announcing that it is soliciting applications to fill the seats of this council. Applications are due Friday March 7, 2025.

In the following **SUPPLEMENTARY INFORMATION** section, NOAA provides details regarding ONMS, the role of advisory councils, and contact information for CHNMS.

II. Office of National Marine Sanctuaries (ONMS)

ONMS serves as the trustee for a network of underwater parks encompassing more than 629,000 square miles of marine and Great Lakes waters from Washington State to the Florida

Keys, and from Lake Huron to American Samoa. The network includes a system of 17 national marine sanctuaries and the Papahānaumokuākea and Rose Atoll marine national monuments. National marine sanctuaries protect our nation's most vital coastal and marine natural and cultural resources, and through active research, management, and public engagement, sustain healthy environments that are the foundation for thriving communities and stable economies.

One of the many ways ONMS ensures public participation in the designation and management of national marine sanctuaries is through the formation of advisory councils. Advisory councils are community-based groups established to provide advice and recommendations to ONMS on issues including management, science, service, and stewardship, as well as to serve as liaisons between their constituents in the community and the site. Pursuant to section 315(a) of the NMSA, advisory councils are exempt from the requirements of the Federal Advisory Committee Act. Additional information on ONMS and its advisory councils can be found at *https://sanctuaries.noaa.gov.*

III. Advisory Council Membership

Under section 315 of the NMSA, advisory council members may be appointed from among: (1) Persons employed by Federal or State agencies with expertise in natural resources management; (2) members of relevant regional fishery management councils; and (3) representatives of local user groups, conservation and other public interest organizations, scientific organizations, educational organizations, or others interested in the protection and multiple use management of sanctuary resources (16 U.S.C. 1455a(b)).

The charter for each advisory council defines the number and type of seats and positions on the council. The advisory council charter for CHNMS identifies the following non-governmental voting seat types: Indigenous Cultural Knowledge; Public-at-Large (San Luis Obispo County, Santa Barbara County); Conservation; Education; Research; Tourism and Recreation; Ports, Harbors, and Maritime Transportation; Offshore Energy and Telecommunications; Commercial Fishing; and Recreational Fishing. Additionally, the charter identifies the following governmental voting seat types: Santa Ynez Band of Chumash Indians; local San Luis Obispo County; and Santa Barbara County representatives; State representative.

Additionally, the council will have non-voting seats for: Bureau of Ocean Energy Management; Bureau of Safety and Environmental Enforcement; NOAA's National Marine Fisheries Service; U.S. Coast Guard; Department of Defense; U.S. Forest Service; California Department of Fish and Wildlife; California Coastal Commission; California State Lands Commission; Central Coast Regional Water Quality Control Board; California State Parks. The council will also have a non-voting Student Leadership seat for students over the age of 18.

To the extent more representation is needed, NOAA intends to work with the advisory council to establish an Indigenous Cultures Advisory Panel as a working group of the advisory council with adequate space for Indigenous community members and others. NOAA would respectfully expect this group to create unique and essential advice and guidance that is informed by knowledge of local Indigenous culture. More information about the working group and its establishment will be available after the advisory council is appointed. NOAA encourages interested individuals to attend advisory council meetings and review the council's website and posted meeting notes to learn more about the planned Indigenous Cultures Advisory Panel. NOAA also encourages interested individuals to apply to the advisory council's Indigenous Cultural Knowledge seats, once applications are made available.

For the CHNMS advisory council, applicants will be chosen based upon their particular expertise and experience in relation to the seat for which they are applying; community and professional affiliations; views regarding the protection and management of marine or Great Lakes resources; and possibly (though not required) the length of residence in the area affected by the site. Council members and alternates for CHNMS serve two and half or three-year terms, as reflected in the signed charter.

More information on advisory council membership and processes, and materials related to the purpose, policies, and operational requirements for advisory councils can be found in the charter for a particular advisory council (*https://sanctuaries.noaa.gov/management/ac/council_charters.html*) and the National Marine Sanctuary Advisory Council Implementation Handbook (*https://nmssanctuaries.blob.core.windows.net/sanctuaries-prod/media/docs/2022-sanctuary-advisory-council-handbook.pdf*). For more information about the new advisory council for CHNMS, including seat descriptions and application materials, please visit *https://sanctuaries.noaa.gov/chumash-heritage/advisory/.*

Privacy Act Statement

Authority. The collection of information concerning the solicitation for applications for sanctuary advisory councils is authorized under the NMSA, 16 U.S.C. 1445a, and Executive Order 13178, and in accordance with the Privacy Act of 1974, as amended, (Privacy Act, 5 U.S.C. 552a).

Purposes. The collection of names, contact information, professional information, qualifications, and answers to the application questions is required in order for ONMS to evaluate and appoint members to the sanctuary advisory councils. The information collected will be reviewed by NOAA employees, and may also be reviewed by current sanctuary advisory council members as part of the evaluation process.

Routine Uses. NOAA will use the application information for the purposes set forth above. The Privacy Act authorizes disclosure of the collected information for the following purposes: to NOAA staff for work-related purposes; for other purposes as set forth in the Privacy Act; and for routine uses published in one or more of the following Privacy Act System of Records Notices, as applicable: COMMERCE/DEPT–11, Candidates for Membership, Members, and Former Members of Department of Commerce Advisory Committees, available at *https://www.commerce.gov/opog/privacy/SORN/SORN-DEPT-11;* COMMERCE/DEPT–18, Employees Personnel Files Not Covered by Notices of Other Agencies, available at *https://www.commerce.gov/opog/privacy/SORN/SORN-DEPT-18;* and OPM/GOVT–1, General Personnel Records, available at *https://www.opm.gov/information-management/privacy-policy/sorn/opm-sorn-govt-1-general-personnel-records.pdf,* which cover certain records regarding Federal employees and may also cover records of individuals who are not Federal employees who, through their service on a sanctuary advisory council, may be considered as volunteers providing gratuitous services to the agency without compensation; and, for individuals who are also members of a Regional Fishery Management Council, COMMERCE/NOAA–13, Personnel, Payroll, Travel, and Attendance Records of the Regional Fishery Management Councils.

Effects of Not Providing Information. Providing the application information is

voluntary; however, if the information is not provided, the individual will not be considered for appointment as a member of a sanctuary advisory council.

Consent. By submitting an application to ONMS for appointment to a sanctuary advisory council, you are consenting to the use and disclosure of the information for the purposes and routine uses described above. However, if you prefer that your application be reviewed by NOAA employees only and not disclosed to current council members as part of the evaluation process, please contact the sanctuary advisory council coordinator to request internal review only, which will not result in any disadvantage or impact regarding your candidacy, or for any questions regarding this Privacy Act Statement.

Paperwork Reduction Act

ONMS has a valid Office of Management and Budget (OMB) control number (0648–0397) for the collection of public information related to the processing of ONMS national marine sanctuary advisory council applications across the National Marine Sanctuary System. Establishing a sanctuary advisory council for CHNMS fits within the estimated reporting burden under that control number. See *https://www.reginfo.gov/public/do/PRASearch* (Enter Control Number 0648–0397). Therefore, ONMS will not request an update to the reporting burden certified for OMB control number 0648–0397.

Send comments regarding this burden estimate, or any other aspect of this data collection, including suggestions for reducing the burden, to: Office of National Marine Sanctuaries, 1305 East West Highway, N/NMS, Silver Spring, Maryland 20910.

Notwithstanding any other provisions 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 Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.,* unless that collection of information displays a currently valid OMB control number. The OMB control number is #0648–0397.

Authority: 16 U.S.C. 1431 *et seq.*

John Armor,

Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2024–30427 Filed 1–6–25; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE519]

Magnuson-Stevens Act Provisions; Fisheries Off West Coast States; Pacific Highly Migratory Species; Opening of Tier 9 Application Period

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

ACTION: Notice; permit application period opening.

SUMMARY: NMFS announces the opening of the permit application period for initial issuance of limited entry deep-set buoy gear permits under qualification tier 9. Authorized through implementation of Amendment 6 to the Fishery Management Plan (FMP) for U.S. West Coast Fisheries for Highly Migratory Species (HMS) and its implementing regulations, tier 9 was established as the final tier in a ranking system for issuance of limited entry deep-set buoy gear permits. Tier 9 permits for deep-set buoy gear will be available through the National Permits System.

DATES: The application period for initial issuance of deep-set buoy gear permits issued under tier 9 is February 1 through March 31, 2025.

ADDRESSES: This notice is accessible via the internet at the Office of the Federal Register website at *https://www.federalregister.gov.* Background information on Amendment 6 to the HMS FMP and supporting documents are available at the NOAA Fisheries West Coast Region website at *https://www.fisheries.noaa.gov/region/west-coast.*

FOR FURTHER INFORMATION CONTACT: Karen Palmigiano, *karen.palmigiano@noaa.gov* or 206–526–4491.

SUPPLEMENTARY INFORMATION:

Background

The FMP for U.S. West Coast Fisheries for HMS and its implementing regulations at title 50 in the Code of Federal Regulations, part 660, subpart K, regulate commercial and recreational fishing for HMS in the U.S. exclusive economic zone off the coasts of Washington, Oregon, and California and in adjacent high seas waters. NMFS published Amendment 6 and its implementing regulations on May 8, 2023 (88 FR 29545). Amendment 6 authorizes deep-set buoy gear (DSBG) as an additional gear type for catching swordfish and other HMS in Federal waters off of California and Oregon. The Pacific Fishery Management Council recommended that NOAA Fisheries authorize DSBG as an additional commercial gear type to improve the economic viability of the West Coast-based swordfish fishery while minimizing bycatch to the extent practicable. The regulations also established a limited entry (LE) regime for ''phased-in'' permitting of DSBG fishing within Federal waters of the Southern California Bight (see 50 CFR 660.707(g)). Tier 9 is the final phase of that LE permit regime.

Tier 9 Permits

As required by the regulations at § 660.707(g)(12), once the list of initial approved qualifiers for tiers 1 through 8 is exhausted, NMFS may begin accepting applications under tier 9. Additionally, as required by regulations, NMFS must announce the opening of tier 9 in the **Federal Register**. This notice serves as that announcement.

Therefore, beginning on February 1, 2025, and ending on March 31, 2025, NMFS will accept applications for initial issuance of LE DSBG permits under tier 9. NMFS will continue to accept applications for tier 9 permits on an annual basis and issue up to 25 permits per year until a total of 300 LE DSBG permits are issued, unless NMFS determines that the maximum number of permits should be fewer than 300 and publishes a subsequent rulemaking. The process for initial issuance of LE DSBG permits to applicant that qualify under tier 9, which can be found at § 660.707(g)(12), is summarized below.

To qualify for a LE DSBG permit under tier 9, an applicant must be a ''person'' as defined at § 660.702 and must not already own a LE DSBG permit either individually or as a shareholder in a business which owns a LE DSBG permit.

To apply for a LE DSBG permit under tier 9 in 2025, a person must submit a complete application to NMFS through the National Permits System website no later than 11:59 p.m. Pacific daylight time on March 31, 2025. A complete initial issuance application package consists of the following: a completed initial issuance application form, which may include ownership interest for businesses, and as required under § 660.707(g)(3)(ii); a current copy of the U.S. Coast Guard Documentation Form or State registration form for the vessel that will be registered to the permit; and payment of required fees. NMFS may require additional documentation as it deems necessary to make a determination on the application. The

initial issuance application package will be considered incomplete until the required information is submitted. NMFS will decline to act on an incomplete application.

NMFS will issue LE DSBG permits to approved applicants under tier 9 on a first come, first served basis, according to the date and time that their application was submitted through the National Permits System. NMFS will issue up to 25 permits each year. If NMFS approves more than 25 applications in a single year, the approved applicants above 25 (who were not issued a permit) will receive priority for permit issuance the following year, according to the date and time that their complete applications were received.

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

Dated: December 17, 2024.

Kelly Denit,

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

[FR Doc. 2024–30443 Filed 1–6–25; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE481]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the City of Hoonah's Cargo Dock Project, Hoonah, Alaska

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

ACTION: Notice; proposed incidental harassment authorization; request for comments on proposed authorization and possible renewal.

SUMMARY: NMFS has received a request from the City of Hoonah (Hoonah) for authorization to take marine mammals incidental to pile driving and removal activities associated with the Hoonah Cargo Dock project in Hoonah, Alaska. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to incidentally take marine mammals during the specified activities. NMFS is also requesting comments on a possible one-time, 1-year renewal that could be issued under certain circumstances and if all requirements are met. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorization and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than February 6, 2025.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service and should be submitted via email to *ITP.wachtendonk@noaa.gov*. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities.* In case of problems accessing these documents, please call the contact listed below.

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments, including all attachments, must not exceed a 25-megabyte file size. All comments received are a part of the public record and will generally be posted online at *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Rachel Wachtendonk, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are proposed or, if the taking is limited to harassment, a notice of a proposed IHA is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as ''mitigation''); and requirements pertaining to the monitoring and reporting of the takings. The definitions of all applicable MMPA statutory terms used above are included in the relevant sections below and can be found in section 3 of the MMPA (16 U.S.C. 1362) and NMFS regulations at 50 CFR 216.103.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an IHA) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NAO 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has preliminarily determined that the issuance of the proposed IHA qualifies to be categorically excluded from further NEPA review.

Summary of Request

May 10, 2024, NMFS received a request from Hoonah for an IHA to take marine mammals incidental to pile driving and removal activities associated with the Hoonah Cargo Dock project in Hoonah, Alaska. Following NMFS' review of the application, Hoonah submitted a revised versions on September 10, 2024 and October 15, 2024. The application was deemed adequate and complete on October 22, 2024. Hoonah's request is for take of 8 species of marine mammals by Level B harassment and, for a subset of these species, Level A harassment. Neither Hoonah nor NMFS expect serious injury

or mortality to result from this activity and, therefore, an IHA is appropriate.

NMFS previously issued an IHA to Hoonah for the Hoonah Cargo Dock project (86 FR 27410, May 20, 2021), and later changed the effective dates of the IHA in a re-issuance (87 FR 27571, May 9, 2022). However, due to COVID and inflation no work under the IHA was conducted. Since then, Hoonah has made several changes to their project plan and, therefore, a new IHA is appropriate.

Description of Proposed Activity

Overview

Hoonah is proposing to install a cargo dock at the Hoonah Marine Industrial Center (HMIC) in Hoonah, Alaska (figure 1). The purpose of this project is to install a dock that will enable barges to land, unload, and load during all tidal conditions and seasons. The project is needed to allow for the safe, reliable, and economical transport of freight to and from Hoonah, which is only accessible by air and sea. The construction of the sheet pile cargo dock, barge ramp, and breasting dolphins will require impact and vibratory pile installation and down-the-hole (DTH) drilling (referred to as tension anchoring).

Sounds resulting from pile driving, pile removal, and tension anchoring may result in the incidental take of marine mammals by Level A and Level B harassment in the form of auditory injury or behavioral harassment. Underwater sound would be constrained to Port Fredrick and would be truncated by land masses in the inlet. Construction activities would start in September 2025 and last 5 months.

Dates and Duration

The proposed IHA would be effective from September 1, 2025 through August 31, 2026. Vibratory and impact pile driving and tension anchoring are expected to start in September 2025 and take 107 days over a span of 5 months. All pile driving and removal would be completed during daylight hours.

Specific Geographic Region

The project would take place at the HMIC in Hoonah, Alaska, which is located within Port Fredrick on Icy Strait. The proposed dock would be constructed at an existing barge ramp, adjacent to the Hoonah ferry terminal and tank farm.

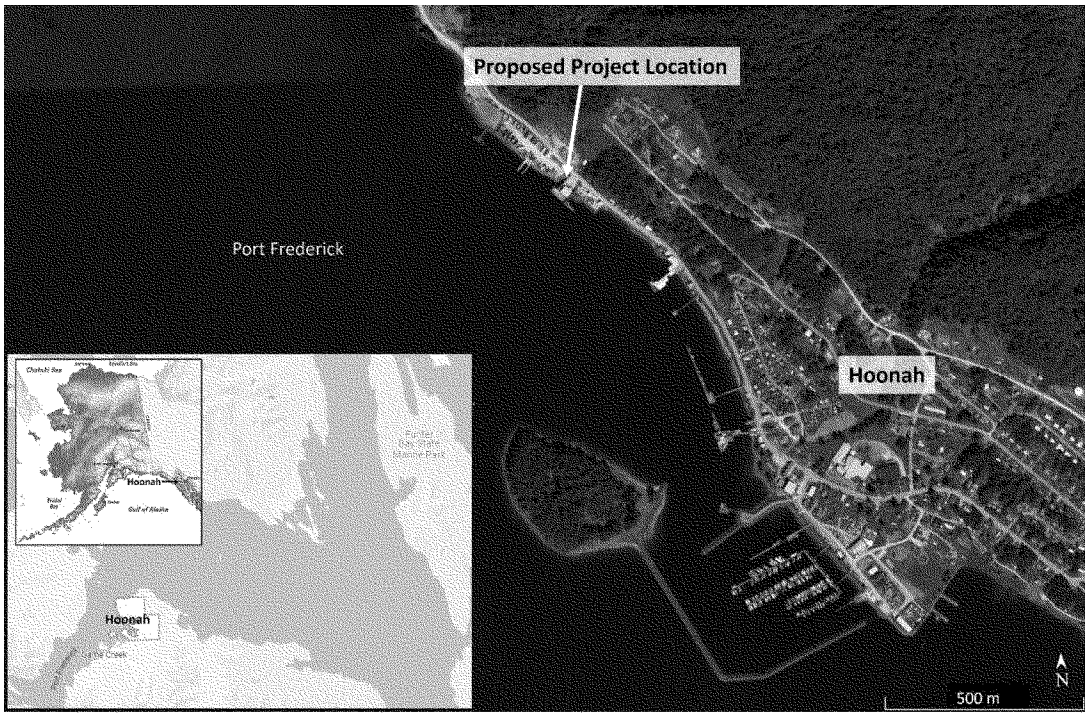

Figure 1 -- Map of Proposed Project Area in Hoonah, Alaska

Detailed Description of the Specified Activity

The construction of the sheet pile cargo dock, barge ramp, and breasting dolphins will include the installation of 542 (330 linear feet (ft), or 100.6 linear meters (m)) steel sheet piles, 5 steel wye piles, 1 steel X pile, 3 20-inch (in), or 0.51-m steel fender piles, 2 16-in (0.41 m) fender piles, 7 H-piles, 4 36-in (0.91 m) steel pipe piles, and 6 36-in (0.91 m) steel batter piles. The installation and removal of 50 temporary 24-in (0.61 m) steel pipe piles will be completed to support the permanent pile installation. Piles will be installed with vibratory and impact hammers, and temporary piles will be removed with a vibratory hammer. 8-to-10-in (0.20 to 0.25 m) steel pipe casings will be placed in each steel pipe/batter piles as tension anchors and set with tension anchoring. Table 1 provides a summary of the pile driving activities.

TABLE 1—NUMBER AND TYPE OF PILES TO BE INSTALLED AND REMOVED

Activity	Pile type and size	Number of piles	Method	Piles per day	Total days
Installation	24-in temporary steel pipe pile	50	Vibratory	6	9
	Steel sheet pile	542		30	19

TABLE 1—NUMBER AND TYPE OF PILES TO BE INSTALLED AND REMOVED—Continued

Activity	Pile type and size	Number of piles	Method	Piles per day	Total days
	Steel wye pile	5		2	3
	Steel X pile	1		1	1
	20-in steel fender pile	3		3	1
	16-in steel fender pile	2		2	1
	Steel H-pile	7		2	4
	36-in steel pipe pile	4		2	2
	36-in steel batter pile	6		2	2
	Steel sheet pile	542	Impact	15	36
	Steel wye pile	5		2	3
	Steel X pile	1		1	1
	20-in steel fender pile	3		3	1
	16-in steel fender pile	2		2	1
	Steel H-pile	7		2	4
	36-in steel pipe pile	4		2	2
	36-in steel batter pile	6		4	2
	8-to-10-in pipe casing drilling	10	Tension Anchoring	2	5
Removal	24-in temporary steel pipe pile	50	Vibratory	6	9

Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see Proposed Mitigation and Proposed Monitoring and Reporting).

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. NMFS fully considered all of this information, and we refer the reader to these descriptions, instead of reprinting the information. Additional information regarding population trends and threats may be found in NMFS' Stock Assessment Reports (SARs; *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS' website (*https://www.fisheries.noaa.gov/find-species).*

Table 2 lists all species or stocks for which take is expected and proposed to be authorized for this activity and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS' SARs). While no serious injury or mortality is anticipated or proposed to be authorized here, PBR and annual serious injury and mortality (M/SI) from anthropogenic sources are included here as gross indicators of the status of the species or stocks and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS' stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS' U.S. Alaska and Pacific SARs. All values presented in table 2 are the most recent available at the time of publication and are available online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments.*

TABLE 2—SPECIES [1] LIKELY IMPACTED BY THE SPECIFIED ACTIVITIES

Common name	Scientific name	Stock	ESA/MMPA status; strategic (Y/N) [2]	Stock abundance (CV, N_{min}, most recent abundance survey) [3]	PBR	Annual M/SI [4]
Order Artiodactyla—Cetacea—Mysticeti (baleen whales)						
Family Balaenopteridae (rorquals)						
Humpback Whale	*Megaptera novaeangliae*	Mainland Mexico—CA/OR/WA	T, D, Y	3,477 (0.101, 3,185, 2018).	43	22
		Hawai'i	-, -, N	11,278 (0.56, 7,265, 2020).	127	27.09
Minke Whale	*Balaenoptera acutorostrata*	AK	-, -, N	N/A (N/A, N/A, N/A) [5]	UND	0
Odontoceti (toothed whales, dolphins, and porpoises)						
Family Delphinidae						
Killer whale	*Orcinus orca*	Eastern North Pacific Alaska Resident.	-, -, N	1,920 (N/A, 1,920, 2019) [6].	19	1.3
		Eastern Northern Pacific Northern Resident.	-, -, N	302 (N/A, 302, 2018) [6]	2.2	0.2
		West Coast Transient	-, -, N	349 (N/A, 349, 2018) [7]	3.5	0.4

TABLE 2—SPECIES [1] LIKELY IMPACTED BY THE SPECIFIED ACTIVITIES—Continued

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) [2]	Stock abundance (CV, N_{min}, most recent abundance survey) [3]	PBR	Annual M/SI [4]
Pacific White-Sided Dolphin	*Lagenorhynchus obliquidens*	N Pacific	-, -, N	26,880 (N/A, N/A, 1990)	UND	0
Family Phocoenidae (porpoises)						
Dall's Porpoise	*Phocoenoides dalli*	AK	-, -, N	UND (UND, UND, 2015) [8].	UND	37
Harbor Porpoise	*Phocoena phocoena*	Northern Southeast Alaska Inland Waters [9].	-, -, N	1,619 (0.26, 1,250, 2019)	13	5.6
Order Carnivora—Pinnipedia						
Family Otariidae (eared seals and sea lions)						
Steller Sea Lion	*Eumetopias jubatus*	Western	E, D, Y	49,837 (N/A, 49,837, 2022) [10].	299	267
		Eastern	-, -, N	36,308 (N/A, 36,308, 2022) [11].	2,178	93.2
Family Phocidae (earless seals)						
Harbor Seal	*Phoca vitulina*	Glacier Bay/Icy Strait	-, -, N	7,455 (N/A, 6,680, 2017)	120	104

[1] Information on the classification of marine mammal species can be found on the web page for The Society for Marine Mammalogy's Committee on Taxonomy (*https://marinemammalscience.org/science-and-publications/list-marine-mammal-species-subspecies/*).

[2] ESA status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[3] NMFS marine mammal SARs online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports-region.* CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance. In some cases, CV is not applicable.

[4] These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

[5] Reliable population estimates are not available for this stock. Please see Friday *et al.* (2013) and Zerbini *et al.* (2006) for additional information on numbers of minke whales in Alaska.

[6] N_{est} is based upon counts of individuals identified from photo-ID catalogs.

[7] N_{est} is based upon count of individuals identified from photo-ID catalogs in analysis of a subset of data from 1958–2018.

[8] The best available abundance estimate is likely an underestimate for the entire stock because it is based upon a survey that covered only a small portion of the stock's range.

[9] New stock split from Southeast Alaska stock.

[10] Nest is best estimate of counts, which have not been corrected for animals at sea during abundance surveys. Estimates provided are for the United States only. The overall N_{min} is 73,211 and overall PBR is 439.

[11] N_{est} is best estimate of counts, which have not been corrected for animals at sea during abundance surveys. Estimates provided are for the United States only.

As indicated above, all 8 species (with 12 managed stocks) in table 2 temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur. All species that could potentially occur in the project area are included in table 6 of the IHA application. While gray whales and sperm whales have been documented in the area, the temporal and/or spatial occurrence of these species is such that take is not expected to occur, and they are not discussed further beyond the explanation provided here. Gray whales are considered to be very rare (no local knowledge of sightings in the project area) and sperm whales are considered to be rare (no sightings in recent years) within the project area.

Additional information relevant to our analyses (beyond that included above, in the application, and on NMFS website) is included below, as appropriate. In addition, the Northern sea otter (*Enhydra lutris kenyoni*) may be found in the project area. However, sea otters are managed by the U.S. Fish and Wildlife Service and are not considered further in this document.

Humpback Whale

The Mainland Mexico—CA/OR/WA and Hawaii stocks of humpback whale occur in the project area. Wild *et al.* (2023) identified Glacier Bay and Icy Strait as a Biologically Important Area (BIA) for humpback whales for feeding during the months of May through October, with an importance score of two (indicating an area of moderate importance), an intensity score of two (indicating an area of moderate comparative significance) and a data support score of three (highest relative confidence in the available supporting data). Humpback whales have been observed within Port Fredrick and Icy Strait, with most sightings occurring from late May through October (SolsticeAK 2024).

Steller Sea Lion

Steller sea lions were listed as threatened range-wide under the ESA on November 26, 1990 (55 FR 49204). Steller sea lions were subsequently partitioned into the western and eastern Distinct Population Segments (DPSs; western and eastern stocks) in 1997 (62 FR 24345, May 5, 1997). The eastern DPS remained classified as threatened until it was delisted in November 2013. The western DPS (those individuals west of the 144° W longitude or Cape Suckling, Alaska) was upgraded to endangered status following separation of the DPSs, and it remains endangered today. There is regular movement of both DPSs across this 144° W longitude boundary especially within a core mixing zone (Jemison *et al.,* 2013). The proposed project is located outside of the known core mixing zone of eastern DPS and western DPS Steller sea lions; however, western DPS animals have been recorded within the Lynn Canal extended mixing zone which includes the proposed project area (Hastings *et al.,* 2020; *Jemison et al.,* 2013). Therefore, while both DPSs could be observed within the project area, most are expected to be from the unlisted eastern DPS.

Steller sea lions do not follow traditional migration patterns, but will move from offshore rookeries in the summer to more protected haulouts closer to shore in the winter. They use rookeries and haulouts as resting spots as they follow prey movements and take foraging trips for days, usually within a few miles (mi) of their rookery or haulout. They are generalist marine predators and opportunistic feeders based on seasonal abundance and location of prey. Steller sea lions forage in nearshore as well as offshore areas, following prey resources. They are highly social and are often observed in large groups while hauled out but alone or in small groups when at sea (NMFS 2023b).

Steller sea lions are common in the proposed project area and reside in the area year-round. The nearest rookery to the proposed project is White Sisters (~72 kilometers (km) (44.5 mi southwest of project) and the nearest major haulout is The Sisters (13 km (8 mi) northeast of project) (AFSC 2023).

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007, 2019) recommended that marine mammals be divided into hearing groups based on directly measured (behavioral or auditory evoked potential techniques) or estimated hearing ranges (behavioral response data, anatomical modeling, *etc.*). Generalized hearing ranges were chosen based on the ~65 decibel (dB) threshold from composite audiograms, previous analyses in NMFS (2018), and/or data from Southall *et al.* (2007) and Southall *et al.* (2019). We note that the names of two hearing groups and the generalized hearing ranges of all marine mammal hearing groups have been recently updated (NMFS 2024) as reflected below in in table 3.

TABLE 3—MARINE MAMMAL HEARING GROUPS

[NMFS, 2024a]

Hearing group	Generalized hearing range *
UNDERWATER:	
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 36 * kHz.
High-frequency (HF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
Very High-frequency (VHF) cetaceans (true porpoises, *Kogia,* river dolphins, Cephalorhynchid, *Lagenorhynchus cruciger* & *L. australis*).	200 Hz to 165 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	40 Hz to 90 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 68 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.,* all species within the group), where individual species' hearing ranges may not be as broad. Generalized hearing range chosen based on ~65 dB threshold from composite audiogram, previous analysis in NMFS 2018, and/or data from Southall *et al.,* 2007; Southall *et al.,* 2019. Additionally, animals are able to detect very loud sounds above and below that ''generalized'' hearing range.

For more detail concerning these groups and associated frequency ranges, please see NMFS (2024a) for a review of available information.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section provides a discussion of the ways in which components of the specified activity may impact marine mammals and their habitat. The Estimated Take of Marine Mammals section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The Negligible Impact Analysis and Determination section considers the content of this section, the Estimated Take of Marine Mammals section, and the Proposed Mitigation section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and whether those impacts are reasonably expected to, or reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Description of Sound Sources

The marine soundscape is comprised of both ambient and anthropogenic sounds. Ambient sound is defined as the all-encompassing sound in a given place and is usually a composite of sound from many sources both near and far. The sound level of an area is defined by the total acoustical energy being generated by known and unknown sources. These sources may include physical (*e.g.,* waves, wind, precipitation, earthquakes, ice, atmospheric sound), biological (*e.g.,* sounds produced by marine mammals, fish, and invertebrates), and anthropogenic sound (*e.g.,* vessels, dredging, aircraft, construction).

The sum of the various natural and anthropogenic sound sources at any given location and time—which comprise ''ambient'' or ''background'' sound—depends not only on the source levels (as determined by current weather conditions and levels of biological and shipping activity) but also on the ability of sound to propagate through the environment. In turn, sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor, and is frequency-dependent. As a result of the dependence on a large number of varying factors, ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location can vary by 10 to 20 dB from day to day (Richardson *et al.,* 1995). The result is that, depending on the source type and its intensity, sound from the specified activity may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals.

In-water construction activities associated with the project would include impact pile installation, vibratory pile installation and removal, and tension anchoring. Impact hammers typically operate by repeatedly dropping and/or pushing a heavy piston onto a pile to drive the pile into the substrate. Sound generated by impact hammers is impulsive, characterized by rapid rise times and high peak levels, a potentially injurious combination

(Hastings and Popper, 2005). Vibratory hammers install piles by vibrating them and allowing the weight of the hammer to push them into the sediment. Vibratory hammers typically produce less sound (*i.e.,* lower levels) than impact hammers. Peak SPLs may be 180 dB or greater but are generally 10 to 20 dB lower than SPLs generated during impact pile driving of the same-sized pile (Oestman *et al.,* 2009; California Department of Transportation (CALTRANS), 2015, 2020). Sounds produced by vibratory hammers are non-impulsive; the rise time is slower, reducing the probability and severity of injury, and the sound energy is distributed over a greater amount of time (Nedwell and Edwards, 2002; Carlson *et al.,* 2005). Tension anchoring through DTH systems would also be used during the proposed construction. A DTH hammer is essentially a drill bit that drills through the bedrock using a rotating function like a normal drill, in concert with a hammering mechanism operated by a pneumatic (or sometimes hydraulic) component integrated into the DTH hammer to increase speed of progress through the substrate (*i.e.,* it is similar to a ''hammer drill'' hand tool). The sounds produced by the DTH methods contain both a continuous non-impulsive component from the drilling action and an impulsive component from the hammering effect. Therefore, NMFS treats DTH systems as both impulsive and continuous, non-impulsive sound source types simultaneously.

The likely or possible impacts of Hoonah's proposed activity on marine mammals could involve both non-acoustic and acoustic stressors. Potential non-acoustic stressors could result from the physical presence of the equipment and personnel; however, any impacts to marine mammals are expected to be primarily acoustic in nature.

Acoustic Impacts

The introduction of anthropogenic noise into the aquatic environment from pile driving is the primary means by which marine mammals may be harassed from the proposed activity. In general, animals exposed to natural or anthropogenic sound may experience physical and psychological effects, ranging in magnitude from none to severe (Southall *et al.,* 2007). In general, exposure to pile driving and tension anchoring noise has the potential to result in an auditory threshold shift (TS) and behavioral reactions (*e.g.,* avoidance, temporary cessation of foraging and vocalizing, changes in dive behavior). Exposure to anthropogenic noise can also lead to non-observable physiological responses, such as an increase in stress hormones. Additional noise in a marine mammal's habitat can mask acoustic cues used by marine mammals to carry out daily functions such as communication and predator and prey detection. The effects of pile driving noise on marine mammals are dependent on several factors, including, but not limited to, sound type (*e.g.,* impulsive vs. non-impulsive), the species, age and sex class (*e.g.,* adult male vs. mom with calf), duration of exposure, the distance between the pile and the animal, received levels, behavior at time of exposure, and previous history with exposure (Wartzok *et al.,* 2004; Southall *et al.,* 2007). Here we discuss physical auditory effects (threshold shifts) followed by behavioral effects and potential impacts on habitat.

NMFS defines a noise-induced TS as a change, usually an increase, in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2018). The amount of TS is customarily expressed in dB. A TS can be permanent or temporary. As described in NMFS (2018), there are numerous factors to consider when examining the consequence of TS, including, but not limited to, the signal temporal pattern (*e.g.,* impulsive or non-impulsive), likelihood an individual would be exposed for a long enough duration or to a high enough level to induce a TS, the magnitude of the TS, time to recovery (seconds to minutes or hours to days), the frequency range of the exposure (*i.e.,* spectral content), the hearing frequency range of the exposed species relative to the signal's frequency spectrum (*i.e.,* how an animal uses sound within the frequency band of the signal; *e.g.,* Kastelein *et al.,* 2014), and the overlap between the animal and the source (*e.g.,* spatial, temporal, and spectral).

Auditory Injury—NMFS defines auditory injury as damage to the inner ear that can result in destruction of tissue . . . which may or may not result in permanent threshold shift (PTS; NMFS, 2024a). NMFS defines PTS as a permanent, irreversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2024a). PTS does not generally affect more than a limited frequency range, and an animal that has PTS has incurred some level of hearing loss at the relevant frequencies; typically, animals with PTS are not functionally deaf (Au and Hastings, 2008; Finneran, 2016). Available data from humans and other terrestrial mammals indicate that a 40-dB threshold shift approximates PTS onset (see Ward *et al.,* 1958, 1959, 1960; Kryter *et al.,* 1966; Miller, 1974; Ahroon *et al.,* 1996; Henderson *et al.,* 2008). PTS levels for marine mammals are estimates, as with the exception of a single study unintentionally inducing PTS in a harbor seal (Kastak *et al.,* 2008), there are no empirical data measuring PTS in marine mammals largely due to the fact that, for various ethical reasons, experiments involving anthropogenic noise exposure at levels inducing PTS are not typically pursued or authorized (NMFS, 2018).

Temporary Threshold Shift—TTS is a temporary, reversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2018). Based on data from cetacean TTS measurements (Southall *et al.,* 2007, 2019), a TTS of 6 dB is considered the minimum TS clearly larger than any day-to-day or session-to-session variation in a subject's normal hearing ability (Schlundt *et al.,* 2000; Finneran *et al.,* 2000, 2002). As described in Finneran (2015), marine mammal studies have shown the amount of TTS increases with cumulative sound exposure level (SEL_{cum}) in an accelerating fashion: At low exposures with lower SEL_{cum}, the amount of TTS is typically small and the growth curves have shallow slopes. At exposures with higher SEL_{cum}, the growth curves become steeper and approach linear relationships with the noise SEL.

Depending on the degree (elevation of threshold in dB), duration (*i.e.,* recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious (similar to those discussed in auditory masking, below). For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that takes place during a time when the animal is traveling through the open ocean, where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during a time when communication is critical for successful mother/calf interactions could have more serious impacts. We note that reduced hearing sensitivity as a simple function of aging has been observed in marine mammals, as well as humans and other taxa (Southall *et al.,* 2007), so we can infer that strategies

exist for coping with this condition to some degree, though likely not without cost.

Many studies have examined noise-induced hearing loss in marine mammals (see Finneran (2015) and Southall *et al.* (2019) for summaries). TTS is the mildest form of hearing impairment that can occur during exposure to sound (Kryter, 2013). While experiencing TTS, the hearing threshold rises, and a sound must be at a higher level in order to be heard. In terrestrial and marine mammals, TTS can last from minutes or hours to days (in cases of strong TTS). In many cases, hearing sensitivity recovers rapidly after exposure to the sound ends. For pinnipeds in water, measurements of TTS are limited to harbor seals, elephant seals (*Mirounga angustirostris*), bearded seals (*Erignathus barbatus*) and California sea lions (*Zalophus californianus*) (Kastak *et al.,* 1999, 2007; Kastelein *et al.,* 2019a, 2019b, 2021, 2022a, 2022b; Reichmuth *et al.,* 2019; Sills *et al.,* 2020). These studies examined hearing thresholds measured in marine mammals before and after exposure to intense or long-duration sound exposures. The difference between the pre-exposure and post-exposure thresholds can be used to determine the amount of TS at various post-exposure times.

The amount and onset of TTS depends on the exposure frequency. Sounds at low frequencies, well below the region of best sensitivity for a species or hearing group, are less hazardous than those at higher frequencies, near the region of best sensitivity (Finneran and Schlundt, 2013). At low frequencies, onset-TTS exposure levels are higher compared to those in the region of best sensitivity (*i.e.,* a low frequency noise would need to be louder to cause TTS onset when TTS exposure level is higher), as shown for harbor porpoises and harbor seals (Kastelein *et al.,* 2019a, 2019c). Note that in general, harbor seals have a lower TTS onset than other measured pinniped species (Finneran, 2015). In addition, TTS can accumulate across multiple exposures, but the resulting TTS will be less than the TTS from a single, continuous exposure with the same SEL (Mooney *et al.,* 2009; Finneran *et al.,* 2010; Kastelein *et al.,* 2014, 2015). This means that TTS predictions based on the total, SEL_{cum} will overestimate the amount of TTS from intermittent exposures, such as sonars and impulsive sources. Nachtigall *et al.* (2018) describe measurements of hearing sensitivity of multiple odontocete species (bottlenose dolphin, harbor porpoise, beluga, and false killer whale (*Pseudorca crassidens*)) when a relatively loud sound was preceded by a warning sound. These captive animals were shown to reduce hearing sensitivity when warned of an impending intense sound. Based on these experimental observations of captive animals, the authors suggest that wild animals may dampen their hearing during prolonged exposures or if conditioned to anticipate intense sounds. Additionally, the existing marine mammal TTS data come from a limited number of individuals within these species.

Relationships between TTS and PTS thresholds have not been studied in marine mammals, but such relationships are assumed to be similar to those in humans and other terrestrial mammals. PTS typically occurs at exposure levels at least several dBs above that inducing mild TTS (*e.g.,* a 40-dB TS approximates PTS onset (Kryter *et al.,* 1966; Miller, 1974), while a 6-dB TS approximates TTS onset (Southall *et al.,* 2007, 2019). Based on data from terrestrial mammals, a precautionary assumption is that the PTS thresholds for impulsive sounds (such as impact pile driving pulses as received close to the source) are at least 6 dB higher than the TTS threshold on a peak-pressure basis and PTS cumulative sound exposure level thresholds are 15 to 20 dB higher than TTS cumulative sound exposure level thresholds (Southall *et al.,* 2007, 2019). Given the higher level of sound or longer exposure duration necessary to cause PTS as compared with TTS, it is considerably less likely that PTS could occur.

Behavioral Harassment—Exposure to noise from pile driving and removal and tension anchoring also has the potential to behaviorally disturb marine mammals. Available studies show wide variation in response to underwater sound; therefore, it is difficult to predict specifically how any given sound in a particular instance might affect marine mammals perceiving the signal. If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, let alone the stock or population. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (*e.g.,* Lusseau and Bejder, 2007; Weilgart, 2007; National Research Council (NRC), 2005).

Disturbance may result in changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior (such as tail/fluke slapping or jaw clapping); or avoidance of areas where sound sources are located. Pinnipeds may increase their haulout time, possibly to avoid in-water disturbance (Thorson and Reyff, 2006). Behavioral responses to sound are highly variable and context-specific and any reactions depend on numerous intrinsic and extrinsic factors (*e.g.,* species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day), as well as the interplay between factors (*e.g.,* Richardson *et al.,* 1995; Wartzok *et al.,* 2003; Southall *et al.,* 2007; Weilgart, 2007; Archer *et al.,* 2010). Behavioral reactions can vary not only among individuals but also within an individual, depending on previous experience with a sound source, context, and numerous other factors (Ellison *et al.,* 2012), and can vary depending on characteristics associated with the sound source (*e.g.,* whether it is moving or stationary, number of sources, distance from the source). In general, pinnipeds seem more tolerant of, or at least habituate more quickly to, potentially disturbing underwater sound than do cetaceans, and generally seem to be less responsive to exposure to industrial sound than most cetaceans. Please see appendices B–C of Southall *et al.* (2007) and Gomez et al. (2016) for a review of studies involving marine mammal behavioral responses to sound.

Habituation can occur when an animal's response to a stimulus wanes with repeated exposure, usually in the absence of unpleasant associated events (Wartzok *et al.,* 2004). Animals are most likely to habituate to sounds that are predictable and unvarying. It is important to note that habituation is appropriately considered as a ''progressive reduction in response to stimuli that are perceived as neither aversive nor beneficial,'' rather than as, more generally, moderation in response to human disturbance (Bejder *et al.,* 2009). The opposite process is sensitization, when an unpleasant experience leads to subsequent responses, often in the form of avoidance, at a lower level of exposure.

As noted above, behavioral state may affect the type of response. For example, animals that are resting may show greater behavioral change in response to disturbing sound levels than animals that are highly motivated to remain in an area for feeding (Richardson *et al.,* 1995; Wartzok *et al.,* 2004; National

Research Council (NRC), 2005). Controlled experiments with captive marine mammals have showed pronounced behavioral reactions, including avoidance of loud sound sources (Ridgway *et al.,* 1997; Finneran *et al.,* 2003). Observed responses of wild marine mammals to loud pulsed sound sources (*e.g.,* seismic airguns) have been varied but often consist of avoidance behavior or other behavioral changes (Richardson *et al.,* 1995; Morton and Symonds, 2002; Nowacek *et al.,* 2007).

Available studies show wide variation in response to underwater sound; therefore, it is difficult to predict specifically how any given sound in a particular instance might affect marine mammals perceiving the signal (*e.g.,* Erbe *et al.,* 2019). If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, let alone the stock or population. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (*e.g.,* Lusseau and Bejder, 2007; Weilgart, 2007; NRC, 2005). However, there are broad categories of potential response, which we describe in greater detail here, that include alteration of dive behavior, alteration of foraging behavior, effects to breathing, interference with or alteration of vocalization, avoidance, and flight.

Changes in dive behavior can vary widely and may consist of increased or decreased dive times and surface intervals as well as changes in the rates of ascent and descent during a dive (*e.g.,* Frankel and Clark, 2000; Costa *et al.,* 2003; Ng and Leung, 2003; Nowacek *et al.,* 2004; Goldbogen *et al.,* 2013a, 2013b, Blair *et al.,* 2016). Variations in dive behavior may reflect interruptions in biologically significant activities (*e.g.,* foraging) or they may be of little biological significance. The impact of an alteration to dive behavior resulting from an acoustic exposure depends on what the animal is doing at the time of the exposure and the type and magnitude of the response.

Disruption of feeding behavior can be difficult to correlate with anthropogenic sound exposure, so it is usually inferred by observed displacement from known foraging areas, the appearance of secondary indicators (*e.g.,* bubble nets or sediment plumes), or changes in dive behavior. In response to playbacks of vibratory pile driving sounds, captive bottlenose dolphins showed changes in target detection and number of clicks used for a trained echolocation task (Branstetter *et al.* 2018). Similarly, harbor porpoises trained to collect fish during playback of impact pile driving sounds also showed potential changes in behavior and task success, though individual differences were prevalent (Kastelein *et al.* 2019d).As for other types of behavioral response, the frequency, duration, and temporal pattern of signal presentation, as well as differences in species sensitivity, are likely contributing factors to differences in response in any given circumstance (*e.g.,* Croll *et al.,* 2001; Nowacek *et al.,* 2004; Madsen *et al.,* 2006; Yazvenko *et al.,* 2007). A determination of whether foraging disruptions incur fitness consequences would require information on or estimates of the energetic requirements of the affected individuals and the relationship between prey availability, foraging effort and success, and the life history stage of the animal.

A flight response is a dramatic change in normal movement to a directed and rapid movement away from the perceived location of a sound source. The flight response differs from other avoidance responses in the intensity of the response (*e.g.,* directed movement, rate of travel). Relatively little information on flight responses of marine mammals to anthropogenic signals exist, although observations of flight responses to the presence of predators have occurred (Connor and Heithaus, 1996; Bowers *et al.,* 2018). The result of a flight response could range from brief, temporary exertion and displacement from the area where the signal provokes flight to, in extreme cases, marine mammal strandings (England *et al.,* 2001). However, it should be noted that response to a perceived predator does not necessarily invoke flight (Ford and Reeves, 2008), and whether individuals are solitary or in groups may influence the response.

Behavioral disturbance can also impact marine mammals in more subtle ways. Increased vigilance may result in costs related to diversion of focus and attention (*i.e.,* when a response consists of increased vigilance, it may come at the cost of decreased attention to other critical behaviors such as foraging or resting). These effects have generally not been demonstrated for marine mammals, but studies involving fishes and terrestrial animals have shown that increased vigilance may substantially reduce feeding rates (*e.g.,* Beauchamp and Livoreil, 1997; Fritz *et al.,* 2002; Purser and Radford, 2011). In addition, chronic disturbance can cause population declines through reduction of fitness (*e.g.,* decline in body condition) and subsequent reduction in reproductive success, survival, or both (*e.g.,* Harrington and Veitch, 1992; Daan *et al.,* 1996; Bradshaw *et al.,* 1998). However, Ridgway *et al.* (2006) reported that increased vigilance in bottlenose dolphins exposed to sound over a 5-day period did not cause any sleep deprivation or stress effects.

Stress Responses—An animal's perception of a threat may be sufficient to trigger stress responses consisting of some combination of behavioral responses, autonomic nervous system responses, neuroendocrine responses, or immune responses (*e.g.,* Seyle, 1950; Moberg, 2000). In many cases, an animal's first and sometimes most economical (in terms of energetic costs) response is behavioral avoidance of the potential stressor. Autonomic nervous system responses to stress typically involve changes in heart rate, blood pressure, and gastrointestinal activity. These responses have a relatively short duration and may or may not have a significant long-term effect on an animal's fitness.

Neuroendocrine stress responses often involve the hypothalamus-pituitary-adrenal system. Virtually all neuroendocrine functions that are affected by stress—including immune competence, reproduction, metabolism, and behavior—are regulated by pituitary hormones. Stress-induced changes in the secretion of pituitary hormones have been implicated in failed reproduction, altered metabolism, reduced immune competence, and behavioral disturbance (*e.g.,* Moberg, 1987; Blecha, 2000). Increases in the circulation of glucocorticoids are also equated with stress (Romano *et al.,* 2004).

The primary distinction between stress (which is adaptive and does not normally place an animal at risk) and ''distress'' is the cost of the response. During a stress response, an animal uses glycogen stores that can be quickly replenished once the stress is alleviated. In such circumstances, the cost of the stress response would not pose serious fitness consequences. However, when an animal does not have sufficient energy reserves to satisfy the energetic costs of a stress response, energy resources must be diverted from other functions. This state of distress will last until the animal replenishes its energetic reserves sufficient to restore normal function.

Relationships between these physiological mechanisms, animal behavior, and the costs of stress responses are well studied through controlled experiments and for both laboratory and free-ranging animals (*e.g.,* Holberton *et al.,* 1996; Hood *et al.,* 1998; Jessop *et al.,* 2003; Krausman *et*

al., 2004; Lankford *et al.,* 2005). Stress responses due to exposure to anthropogenic sounds or other stressors and their effects on marine mammals have also been reviewed (Fair and Becker, 2000; Romano *et al.,* 2002a) and, more rarely, studied in wild populations (*e.g.,* Romano *et al.,* 2002b). For example, Rolland *et al.* (2012) found that noise reduction from reduced ship traffic in the Bay of Fundy was associated with decreased stress in North Atlantic right whales. These and other studies lead to a reasonable expectation that some marine mammals will experience physiological stress responses upon exposure to acoustic stressors and that it is possible that some of these would be classified as ''distress.'' In addition, any animal experiencing TTS would likely also experience stress responses (NRC, 2003), however distress is an unlikely result of this project based on observations of marine mammals during previous, similar projects in the area.

Masking—Sound can disrupt behavior through masking, or interfering with, an animal's ability to detect, recognize, or discriminate between acoustic signals of interest (*e.g.,* those used for intraspecific communication and social interactions, prey detection, predator avoidance, navigation) (Richardson *et al.,* 1995). Masking occurs when the receipt of a sound is interfered with by another coincident sound at similar frequencies and at similar or higher intensity, and may occur whether the sound is natural (*e.g.,* snapping shrimp, wind, waves, precipitation) or anthropogenic (*e.g.,* pile driving, shipping, sonar, seismic exploration) in origin. The ability of a noise source to mask biologically important sounds depends on the characteristics of both the noise source and the signal of interest (*e.g.,* signal-to-noise ratio, temporal variability, direction), in relation to each other and to an animal's hearing abilities (*e.g.,* sensitivity, frequency range, critical ratios, frequency discrimination, directional discrimination, age or TTS hearing loss), and existing ambient noise and propagation conditions. Masking of natural sounds can result when human activities produce high levels of background sound at frequencies important to marine mammals. Conversely, if the background level of underwater sound is high (*e.g.,* on a day with strong wind and high waves), an anthropogenic sound source would not be detectable as far away as would be possible under quieter conditions and would itself be masked.

Airborne Acoustic Effects—Although pinnipeds are known to haul out regularly at two harbor seal haulout sites within Port Fredrick, NMFS expects that incidents of take resulting solely from airborne sound are unlikely due to their proximity. One of the haulouts (CE79A) is located approximately 10 km (6.25 mi) from the project site and is outside of the ensonfied zone for this action. The other (CF39A) is located approximately 3 km (2 mi) from the project site and will be ensonified during some vibratory and impact pile driving activities. Neither of these haulouts are listed as a ''key haulout,'' or a haulout with 50 or more individuals present at the time of survey (AFSC 2024).

Cetaceans are not expected to be exposed to airborne sounds that would result in harassment as defined under the MMPA. Airborne noise would primarily be an issue for pinnipeds that are swimming or hauled out near the project site within the range of noise levels elevated above the acoustic criteria. We recognize that pinnipeds in the water could be exposed to airborne sound that may result in behavioral harassment when looking with their heads above water. Most likely, airborne sound would cause behavioral responses similar to those discussed above in relation to underwater sound. For instance, anthropogenic sound could cause hauled-out pinnipeds to exhibit changes in their normal behavior, such as reduction in vocalizations, or cause them to temporarily abandon the area and move further from the source. However, these animals would likely previously have been ''taken'' because of exposure to underwater sound above the behavioral harassment thresholds, which are generally larger than those associated with airborne sound. Thus, the behavioral harassment of these animals is already accounted for in these estimates of potential take. Therefore, we do not believe that authorization of incidental take resulting from airborne sound for pinnipeds is warranted, and airborne sound is not discussed further here.

Marine Mammal Habitat Effects

Hoonah's construction activities could have localized, temporary impacts on marine mammal habitat by increasing in-water SPLs and slightly decreasing water quality. No net habitat loss is expected, since its proposed location is an existing barge ramp that already experiences frequent vessel traffic and is adjacent to an active road, ferry terminal, dock, boat haulout pier, and boat yard. Construction activities are localized and would likely have temporary impacts on marine mammal habitat through increases in underwater sounds. Increased noise levels may affect acoustic habitat (see masking discussion above) and adversely affect marine mammal prey in the vicinity of the project area (see discussion below). During pile driving activities, elevated levels of underwater noise would ensonify the project area where both fishes and marine mammals may occur and could affect foraging success. Additionally, marine mammals may avoid the area during construction; however, displacement due to noise is expected to be temporary and is not expected to result in long-term effects to the individuals or populations.

Temporary and localized reduction in water quality would occur because of in-water construction activities as well. Most of this effect would occur during the installation and removal of piles when bottom sediments are disturbed. The installation of piles would disturb bottom sediments and may cause a temporary increase in suspended sediment in the project area. In general, turbidity associated with pile installation is localized to about 25-ft (7.6-m) radius around the pile (Everitt *et al.,* 1980). Pinnipeds are not expected to be close enough to the pile driving areas to experience effects of turbidity, and could avoid localized areas of turbidity. Therefore, we expect the impact from increased turbidity levels to be discountable to marine mammals and do not discuss it further.

In-Water Construction Effects on Potential Foraging Habitat

The proposed activities would not result in permanent impacts to habitats used directly by marine mammals outside of the actual footprint of the constructed dock. The total seafloor area affected by pile installation and removal is a very small area compared to the vast foraging area available to marine mammals in Port Fredrick and the surrounding waters. Pile extraction and installation and tension anchoring may have impacts on benthic invertebrate species primarily associated with disturbance of sediments that may cover or displace some invertebrates. The impacts would be temporary and highly localized, and no habitat would be permanently displaced by construction. Therefore, it is expected that impacts on foraging opportunities for marine mammals due to construction of the dock would be minimal.

It is possible that avoidance by potential prey (*i.e.,* fish) in the immediate area may occur due to temporary loss of this foraging habitat. The duration of fish avoidance of this area after pile driving stops is unknown,

but we anticipate a rapid return to normal recruitment, distribution and behavior. Any behavioral avoidance by fish of the disturbed area would still leave large areas of fish and marine mammal foraging habitat in the nearby vicinity in the in the project area and surrounding waters.

Effects on Potential Prey

Construction activities would produce continuous (*i.e.,* vibratory pile driving and tension anchoring) and intermittent (*i.e.,* impact driving and tension anchoring) sounds. Sound may affect marine mammals through impacts on the abundance, behavior, or distribution of prey species (*e.g.,* fish). Marine mammal prey varies by species, season, and location. Here, we describe studies regarding the effects of noise on known marine mammal prey.

Fish utilize the soundscape and components of sound in their environment to perform important functions such as foraging, predator avoidance, mating, and spawning (*e.g.,* Zelick *et al.,* 1999; Fay, 2009). Depending on their hearing anatomy and peripheral sensory structures, which vary among species, fishes hear sounds using pressure and particle motion sensitivity capabilities and detect the motion of surrounding water (Fay *et al.,* 2008). The potential effects of noise on fishes depends on the overlapping frequency range, distance from the sound source, water depth of exposure, and species-specific hearing sensitivity, anatomy, and physiology. Key impacts to fishes may include behavioral responses, hearing damage, barotrauma (pressure-related injuries), and mortality.

Fish react to sounds which are especially strong and/or intermittent low-frequency sounds, and behavioral responses, such as flight or avoidance are the most likely effects. Short duration, sharp sounds can cause overt or subtle changes in fish behavior and local distribution. The reaction of fish to noise depends on the physiological state of the fish, past exposures, motivation (*e.g.,* feeding, spawning, migration), and other environmental factors. Hastings and Popper (2005) identified several studies that suggest fish may relocate to avoid certain areas of sound energy. Additional studies have documented effects of pile driving on fish, although several are based on studies in support of large, multiyear bridge construction projects (*e.g.,* Scholik and Yan, 2001, 2002; Popper and Hastings, 2009). Several studies have demonstrated that impulse sounds might affect the distribution and behavior of some fishes, potentially impacting foraging opportunities or increasing energetic costs (*e.g.,* Fewtrell and McCauley, 2012; Pearson *et al.,* 1992; Skalski *et al.,* 1992; Santulli *et al.,* 1999; Paxton *et al.,* 2017). However, some studies have shown no or slight reaction to impulse sounds (*e.g.,* Pena *et al.,* 2013; Wardle *et al.,* 2001; Jorgenson and Gyselman, 2009; Cott *et al.,* 2012).

SPLs of sufficient strength have been known to cause injury to fishes and fish mortality (summarized in Popper *et al.,* 2014). However, in most fish species, hair cells in the ear continuously regenerate and loss of auditory function likely is restored when damaged cells are replaced with new cells. Halvorsen *et al.* (2012a) showed that a TTS of 4 to 6 dB was recoverable within 24 hours for one species. Impacts would be most severe when the individual fish is close to the source and when the duration of exposure is long. Injury caused by barotrauma can range from slight to severe and can cause death, and is most likely for fish with swim bladders. Barotrauma injuries have been documented during controlled exposure to impact pile driving (Halvorsen *et al.,* 2012b; Casper *et al.,* 2013, 2017).

Fish populations in the proposed project area that serve as marine mammal prey could be temporarily affected by noise from pile installation and removal. The frequency range in which fishes generally perceive underwater sounds is 50 to 2,000 Hz, with peak sensitivities below 800 Hz (Popper and Hastings, 2009). Fish behavior or distribution may change, especially with strong and/or intermittent sounds that could harm fishes. High underwater SPLs have been documented to alter behavior, cause hearing loss, and injure or kill individual fish by causing serious internal injury (Hastings and Popper, 2005).

The greatest potential impact to fishes during construction would occur during impact pile driving and tension anchoring. The duration of impact pile driving would be limited to the final stage of installation (''proofing'') after the pile has been driven as close as practicable to the design depth with a vibratory driver. Only a total of 10 tension anchors will be set over a total of 5 days of construction. In-water construction activities would only occur during daylight hours, allowing fish to forage and transit the project area in the evening. Vibratory pile driving could elicit behavioral reactions from fishes such as temporary avoidance of the area but is unlikely to cause injuries to fishes or have persistent effects on local fish populations. Construction also would have minimal permanent and temporary impacts on benthic invertebrate species, a marine mammal prey source.

The area impacted by the project is relatively small compared to the available habitat in the remainder of Port Fredrick and the surrounding areas, and there are no areas of particular importance that would be impacted by this project. Any behavioral avoidance by fish of the disturbed area would still leave significantly large areas of fish and marine mammal foraging habitat in the nearby vicinity. As described in the preceding, the potential for Hoonah's construction to affect the availability of prey to marine mammals or to meaningfully impact the quality of physical or acoustic habitat is considered to be insignificant.

Estimated Take of Marine Mammals

This section provides an estimate of the number of incidental takes proposed for authorization through the IHA, which will inform NMFS' consideration of ''small numbers,'' the negligible impact determinations, and impacts on subsistence uses.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would primarily be by Level B harassment as use of the acoustic sources (*i.e.,* pile driving and tension anchoring) has the potential to result in disruption of behavioral patterns for individual marine mammals. There is also some potential for auditory injury (Level A harassment) to result, primarily for very high frequency species and phocids because predicted auditory injury zones are larger than for high-frequency species and otariids. The proposed mitigation and monitoring measures are expected to minimize the severity of the taking to the extent practicable.

As described previously, no serious injury or mortality is anticipated or proposed to be authorized for this activity. Below we describe how the proposed take numbers are estimated.

For acoustic impacts, generally speaking, we estimate take by considering: (1) acoustic thresholds above which NMFS believes the best

available science indicates marine mammals will likely be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these factors can contribute to a basic calculation to provide an initial prediction of potential takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.,* previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the proposed take estimates.

Acoustic Criteria

NMFS recommends the use of acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur auditory injury of some degree (equated to Level A harassment). We note that the criteria for auditory injury, as well as the names of two hearing groups, have been recently updated (NMFS 2024a) as reflected below in the Level A Harassment section.

Level B Harassment—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source or exposure context (*e.g.,* frequency, predictability, duty cycle, duration of the exposure, signal-to-noise ratio, distance to the source), the environment (*e.g.,* bathymetry, other noises in the area, predators in the area), and the receiving animals (hearing, motivation, experience, demography, life stage, depth) and can be difficult to predict (*e.g.,* Southall *et al.,* 2007, 2021, Ellison *et al.,* 2012). Based on what the available science indicates and the practical need to use a threshold based on a metric that is both predictable and measurable for most activities, NMFS typically uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS generally predicts that marine mammals are likely to be behaviorally harassed in a manner considered to be Level B harassment when exposed to underwater anthropogenic noise above root-mean-squared pressure received levels (RMS SPL) of 120 dB (referenced to 1 micropascal (re 1 µPa)) for continuous (*e.g.,* vibratory pile driving, drilling) and above RMS SPL 160 dB re 1 µPa for non-explosive impulsive (*e.g.,* seismic airguns) or intermittent (*e.g.,* scientific sonar) sources. Generally speaking, Level B harassment take estimates based on these behavioral harassment thresholds are expected to include any likely takes by TTS as, in most cases, the likelihood of TTS occurs at distances from the source less than those at which behavioral harassment is likely. TTS of a sufficient degree can manifest as behavioral harassment, as reduced hearing sensitivity and the potential reduced opportunities to detect important signals (conspecific communication, predators, prey) may result in changes in behavior patterns that would not otherwise occur.

Hoonah's proposed activity includes the use of continuous (vibratory pile driving, tension anchoring) and impulsive (impact pile driving, tension anchoring) sources, and therefore the RMS SPL thresholds of 120 and 160 dB re 1 µPa are applicable. Tension anchoring has both continuous and intermittent components as discussed in the *Description of Sound Sources* section above. When evaluating Level B harassment, NMFS recommends treating tension anchoring as a continuous source and applying the RMS SPL thresholds of 120 dB re 1 µPa.

Level A harassment—NMFS' Updated Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 3.0) (Updated Technical Guidance, 2024) identifies dual criteria to assess auditory injury (Level A harassment) to five different underwater marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). Hoonah's proposed activity includes the use of impulsive (impact pile driving, tension anchoring) and non-impulsive (vibratory pile driving, tension anchoring) sources. Tension anchoring includes both impulsive and non-impulsive characteristics. When evaluating Level A harassment, NMFS recommends treating tension anchoring as an impulsive source.

The 2024 Updated Technical Guidance criteria include both updated thresholds and updated weighting functions for each hearing group. The thresholds are provided in the table below. The references, analysis, and methodology used in the development of the criteria are described in NMFS' 2024 Updated Technical Guidance, which may be accessed at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance-other-acoustic-tools.*

TABLE 4—THRESHOLDS IDENTIFYING THE ONSET OF AUDITORY INJURY

Hearing group	Auditory injury onset acoustic thresholds * (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	*Cell 1:* $L_{p,0\text{-}pk,flat}$: 222 dB; $L_{E,p,LF,24h}$: 183 dB	*Cell 2:* $L_{E,p,LF,24h}$: 197 dB.
High-Frequency (HF) Cetaceans	*Cell 3:* $L_{p,0\text{-}pk,flat}$: 230 dB; $L_{E,HF,24h}$: 193 dB	*Cell 4:* $L_{E,p,HF,24h}$: 201 dB.
Very High-Frequency (VHF) Cetaceans	*Cell 5:* $L_{pk,0\text{-}pk,flat}$: 202 dB; $L_{E,p,VHF,24h}$: 159 dB	*Cell 6:* $L_{E,p,VHF,24h}$: 181 dB.
Phocid Pinnipeds (PW) (Underwater)	*Cell 7:* $L_{p,0\text{-}pk,flat}$: 223 dB; $L_{E,PW,24h}$: 185 dB	*Cell 8:* $L_{E,p,PW,24h}$: 195 dB.
Otariid Pinnipeds (OW) (Underwater)	*Cell 9:* $L_{p,0\text{-}pk,flat}$: 230 dB; $L_{E,p,OW,24h}$: 185 dB	*Cell 10:* $L_{E,p,OW,24h}$: 199 dB.

* Dual metric criteria for impulsive sounds: Use whichever criteria results in the larger isopleth for calculating AUD INJ onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level criteria associated with impulsive sounds, the PK SPL criteria are recommended for consideration for non-impulsive sources.

Note: Peak sound pressure level ($L_{p,0\text{-}pk}$) has a reference value of 1 µPa (underwater) and 20 µPa (in air), and weighted cumulative sound exposure level ($L_{E,p}$) has a reference value of 1 µPa2s (underwater) and 20 µPa2s (in air). In this table, criteria are abbreviated to be more reflective of International Organization for Standardization standards (ISO 2017; ISO 2020). The subscript "flat" is being included to indicate peak sound pressure are flat weighted or unweighted within the generalized hearing range of marine mammals underwater (*i.e.,* 7 Hz to 165 kHz) or in air (*i.e.,* 42 Hz to 52 kHz). The subscript associated with cumulative sound exposure level criteria indicates the designated marine mammal auditory weighting function (LF, HF, and VHF cetaceans, and PW, OW, PA, and OA pinnipeds) and that the recommended accumulation period is 24 hours. The weighted cumulative sound exposure level criteria could be exceeded in a multitude of ways (*i.e.,* varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these criteria will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that are used in estimating the area ensonified above the acoustic thresholds, including source levels and transmission loss coefficient.

The sound field in the project area is the existing background noise plus additional construction noise from the proposed project. Vessel traffic and other commercial and industrial activities in the project area may contribute to elevated background noise levels which may mask sounds produced by the project. Marine mammals are expected to be affected via sound generated by the primary components of the project (*i.e.,* vibratory pile driving and removal, impact pile driving, and tension anchoring).

Transmission loss (*TL*) is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. *TL* parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition and topography. The general formula for underwater *TL* is:

$TL = B * \mathrm{Log}_{10}(R_1/R_2)$,

where
TL = transmission loss in dB;
B = transmission loss coefficient;
R_1 = the distance of the modeled SPL from the driven pile, and
R_2 = the distance from the driven pile of the initial measurement.

This formula neglects loss due to scattering and absorption, which is assumed to be zero here. The degree to which underwater sound propagates away from a sound source is dependent on a variety of factors, most notably the water bathymetry and presence or absence of reflective or absorptive conditions including in-water structures and sediments. Spherical spreading occurs in a perfectly unobstructed (free-field) environment not limited by depth or water surface, resulting in a 6-dB reduction in sound level for each doubling of distance from the source (20*log[range]). Cylindrical spreading occurs in an environment in which sound propagation is bounded by the water surface and sea bottom, resulting in a reduction of 3 dB in sound level for each doubling of distance from the source (10*log[range]). A practical spreading value of 15 is often used under conditions, such as the project site, where water increases with depth as the receiver moves away from the shoreline, resulting in an expected propagation environment that would lie between spherical and cylindrical spreading loss conditions. Practical spreading loss is assumed here.

The intensity of pile driving sounds is greatly influenced by factors such as the type of piles, hammers, and the physical environment in which the activity takes place. In order to calculate the distances to the Level A harassment and the Level B harassment sound thresholds for the methods and piles being used in this project, the applicant and NMFS used acoustic monitoring data from other locations to develop proxy source levels for the various pile types, sizes and methods. The project includes vibratory, and impact pile installation of steel pipe piles and vibratory removal of steel pipe piles, steel fender piles, steel sheet piles, steel H-piles, steel wye piles, steel X piles, and steel batter piles and tension anchoring drilling. Source levels for each pile size and driving method are presented in table 5.

NMFS recommends treating DTH systems as both impulsive and continuous, non-impulsive sound source types simultaneously. Thus, impulsive thresholds are used to evaluate Level A harassment, and continuous thresholds are used to evaluate Level B harassment. NMFS (2022) outlines its recommended source levels for DTH systems. NMFS has applied that guidance in this analysis (see Table 5 for NMFS' proposed source levels).

TABLE 5—PROXY SOUND SOURCE LEVELS AT 10 m FOR PILE SIZES AND DRIVING METHODS

Pile type	RMS SPL (re 1 μPa)	SEL (re 1 μPa²-sec)	Peak SPL (re 1 μPa)	Source
Vibratory Pile Driving				
Temporary 24-in steel pipe piles.	162	NA	NA	PR1 2023 calculations (cited in NMFS 2023).
20-in steel fender piles	.....	.....	.....	
Steel sheet piles	160	.....	.....	Caltrans 2015 (cited in NMFS 2023).
16-in steel fender piles	155	.....	.....	PR1 2023 calculations (cited in NMFS 2023).
H-piles	150	.....	.....	PR1 2023 calculations (cited in NMFS 2023).
Wye piles	.....	.....	.....	NMFS 2024.
X piles.				
36-in steel pile	166	.....	.....	PR1 2023 calculations (cited in NMFS 2023).
Impact Pile Driving				
20-in steel fender piles	190	177	203	Caltrans 2015 (cited in NMFS 2023).
Steel sheet piles	190	180	205	Caltrans 2015 (cited in NMFS 2023).
16-in steel fender piles	185	175	200	Caltrans 2020 (cited in NMFS 2023).
H-piles	183	170	210	Caltrans 2015 (cited in NMFS 2023).
Wye piles.				
X piles.				
36-in steel pile	193	183	210	Caltrans 2015 & 2020 (cited in NMFS 2023).
Tension Anchoring				
6–8 in anchor hole	156	144	170	NMFS 2022.

All Level B harassment isopleths are reported in Table 6 below. The maximum (underwater) area ensonified above the thresholds for behavioral harassment is 43 km² (16.6 mi²). However, that zone would be truncated

by land masses that would obstruct underwater sound transmission and would be limited to Port Fredrick (see figure 4 in Trident's application).

The ensonified area associated with Level A harassment is more technically challenging to predict due to the need to account for a duration component. Therefore, NMFS developed an optional User Spreadsheet tool to accompany the 2024 Updated Technical Guidance that can be used to relatively simply predict an isopleth distance for use in conjunction with marine mammal density or occurrence to help predict potential takes. We note that because of some of the assumptions included in the methods underlying this optional tool, we anticipate that the resulting isopleth estimates are typically going to be overestimates of some degree, which may result in an overestimate of potential take by Level A harassment. However, this optional tool offers the best way to estimate isopleth distances when more sophisticated modeling methods are not available or practical. For stationary sources such as pile driving, the optional User Spreadsheet tool predicts the distance at which, if a marine mammal remained at that distance for the duration of the activity, it would be expected to incur auditory injury. Inputs used in the optional User Spreadsheet tool, and the resulting estimated isopleths, are reported below.

TABLE 6—NMFS USER SPREADSHEET INPUTS

Pile size and type	Spreadsheet tab used	Weighting factor adjustment (kHz)	Transmission loss coefficient	Number of piles per day	Activity duration per pile (minutes)	Number of strikes per pile
Vibratory Pile Driving						
Temporary 24-in steel pipe piles	A.1 Vibratory pile driving.	2.5	15	6	15	NA
20-in steel fender piles		2.5	15	3	30	NA
Steel sheet piles		2.5	15	30	15	NA
16-in steel fender piles		2.5	15	2	30	NA
H-piles		2.5	15	2	30	NA
Wye piles		2.5	15	3	30	NA
X piles		2.5	15	1	30	NA
36-in steel pipe pile		2.5	15	2	60	NA
36-in steel batter pile		2.5	15	2	60	NA
Impact Pile Driving						
20-in steel fender piles	E.1. Impact pile driving.	2	15	3	30	600
Steel sheet piles		2	15	15	30	200
16-in steel fender piles		2	15	2	30	600
H-piles		2	15	2	30	600
Wye piles		2	15	2	30	200
X piles		2	15	1	30	200
36-in steel pipe pile		2	15	2	60	1,200
36-in steel batter pile		2	15	4	60	1,200
Tension Anchoring						
6–8 in anchor hole	E.2 DTH pile driving.	2	15	2	60	108,000

TABLE 7—CALCULATED LEVEL A AND LEVEL B HARASSMENT ISOPLETHS

Activity	Level A harassment zone (m)					Level B harassment zone (m)
	LF-cetaceans	HF-cetaceans	VHF-cetaceans	Phocids	Otariids	
Vibratory Pile Driving						
Temporary 24-in steel pipe piles	16.4	6.3	13.4	21.1	7.1	7,356.4
20-in steel fender piles						
Steel sheet piles	30.3	11.6	24.8	39.0	13.1	4,641.6
16-in steel fender piles	3.7	1.4	3.0	4.4	1.6	2,154.4
H-piles	1.7	0.7	1.4	2.2	0.7	1,000.0
Wye piles						
X piles	1.1	0.4	0.9	1.4	0.5	
36-in steel pipe pile	31.5	12.1	25.8	40.6	13.7	11,659.1
36-in steel batter pile						
Impact Pile Driving						
20-in steel fender piles	586.1	74.8	907.1	520.7	194.1	1,000.0
Steel sheet piles	1,305.9	166.6	2,020.9	1,160.1	432.4	
16-in steel fender piles	329.1	42.0	509.2	292.3	109.0	462.2
H-piles	152.7	19.5	236.4	135.7	50.6	341.5
Wye piles	73.4	9.4	113.6	65.2	24.3	
X piles	46.3	5.9	71.6	41.1	15.3	
36-in steel pipe pile	1,783.6	227.6	2,760.1	1,584.5	590.6	1,584.9
36-in steel batter pile	2,831.3	361.2	4,381.4	2,515.2	937.6	

TABLE 7—CALCULATED LEVEL A AND LEVEL B HARASSMENT ISOPLETHS—Continued

Activity	Level A harassment zone (m)					Level B harassment zone (m)
	LF-cetaceans	HF-cetaceans	VHF-cetaceans	Phocids	Otariids	
Tension Anchoring						
6–8 in anchor hole	90.0	11.5	139.2	79.9	29.8	2,512.0

Marine Mammal Occurrence and Take Estimation

In this section we provide information about the occurrence of marine mammals, including density or other relevant information which will inform the take calculations.

Consultation with the Hoonah Harbormaster, applications and reports from other nearby in water construction projects, and available scientific literature are used to estimate the occurrence of marine mammals in the action area. Daily occurrence probability of each marine mammal species in the action area is based on historic data of occurrence, seasonality, and group size in Port Frederick and Icy Strait, and other nearby waters.

Here we describe how the information provided above is synthesized to produce a quantitative estimate of the take that is reasonably likely to occur and proposed for authorization. Tables for each species are presented to show the calculation of take during the project. NMFS used the following equations to estimate take.

Incidental take estimate (daily) = group size * groups per day * days of pile driving activity (107 days)

Incidental take estimate (monthly) = group size * groups per month (considered 30 days) * months of pile driving activity (107 days/30 days per month)

Minke Whale

There are a few sightings of minke whales every year, so they could occur every month during the project. They typically occur in groups of two to three individuals (NMFS 2023d). Up to one group of three minke whales are expected to occur in the project area per month. Therefore, using the monthly equation above, NMFS proposes to authorize 11 takes by Level B harassment of minke whales.

The largest Level A harassment zone for minke whales extends 2,831 m from the sound source (table 7). All construction work would be shut down prior to a minke whale entering the Level A harassment zone specific to the in-water activity underway at the time. In consideration of the infrequent occurrence of minke whales in the project area and proposed shutdown requirements, no take by Level A harassment of minke whales is anticipated or proposed for authorization.

Humpback Whale

There are multiple sightings of humpback whales every month, and they could occur every day during the project. They typically occur in groups of one to two individuals (Dahlheim *et al.,* 2009). Up to one group of two humpback whales are expected to occur in the project area per day. Therefore, using the daily equation above, NMFS proposes to authorize 214 takes by Level B harassment of humpback whales. In the project area, it is estimated that the majority of whales (98 percent) would be from the Hawaii DPS and 2 percent will be from the Mexico DPS (Wade 2021; Muto *et al.* 2022). Therefore, of the 214 takes by Level B harassment, NMFS anticipates that 210 takes would be of individuals from the Hawaii DPS and 4 takes of individuals from the Mexico DPS.

The largest Level A harassment zone for humpback whales extends 2,831 m from the sound source (table 7). All construction work would be shut down prior to a humpback whale entering the Level A harassment zone specific to the in-water activity underway at the time. In consideration that humpback whales are most often seen in Icy Strait and the mouth of Port Fredrick and proposed shutdown requirements, no take by Level A harassment is anticipated or proposed for authorization for humpback whales.

Killer Whale

There are multiple sightings of killer whales every year, and they could occur every month during the project. They typically occur in groups of one to five individuals (NMFS 2023e). Up to four groups of five killer whales (*i.e.,* 20 killer whales total) are expected to occur in the project area per month. Therefore, using the monthly equation given above, NMFS proposes to authorize 72 takes by Level B harassment of killer whales.

The largest Level A harassment zone for killer whales extends 361 m from the sound source (table 7). All construction work would be shut down prior to a killer whale entering the Level A harassment zone specific to the in-water activity underway at the time. In consideration of the small size of the Level A harassment zone and proposed shutdown requirements, no take by Level A harassment of killer whales is anticipated or proposed for authorization.

Pacific White-Sided Dolphin

There are a few sightings of Pacific white-sided dolphins every year, but there are no sightings from recent years. However, to avoid underestimating potential impacts from the project, in estimating take, NMFS assumes they could occur every other month (*i.e.,* one group every 60 days) during the project. They occur in groups of 2 to 153 individuals, but are most commonly seen in groups of 23–26 individuals (Dahlheim *et al.,* 2009). NMFS anticipates that up to one group of 26 Pacific white-sided dolphins could occur in the project area every other month. Using the monthly equation above suggests that there could be 47 takes by Level B harassment of Pacific white-sided dolphins. However, since these dolphins can occur in large groups, NMFS proposes to authorize 153 takes by Level B harassment in case a larger pod is observed.

The largest Level A harassment zone for Pacific white-sided dolphins extends 361 m from the sound source (table 7). All construction work would be shut down prior to a Pacific white-sided dolphin entering the Level A harassment zone specific to the in-water activity underway at the time. In consideration of the small size of the Level A harassment zone, proposed shutdown requirements, and infrequent occurrence of Pacific white-sided dolphins, no take by Level A harassment of Pacific white-sided dolphins is anticipated or proposed for authorization.

Dall's Porpoise

There are multiple sightings of Dall's porpoises every year, and they could occur every month during the project. They typically occur in groups of two to five individuals (Dahlheim *et al.,* 2009). NMFS anticipates that up to four groups

of five Dall's porpoises (*i.e.,* 20 Dall's porpoises total) could occur in the project area per month. Therefore, using the monthly equation given above, NMFS proposes to authorize 72 takes by Level B harassment of Dall's porpoises.

The largest Level A harassment zone for Dall's porpoises extends 4,381 m from the sound source (table 7) during impact pile driving. Hoonah would be required to implement shutdowns during all pile driving activities. However, during impact pile driving of the 20-in fender piles, 16-in fender piles, sheet piles, and 36-in piles, the Level A harassment zones for Dall's porpoise extend beyond the shutdown zones, and NMFS anticipates that Level A harassment could occur. Hoonah estimates, and NMFS concurs, that up to four groups of two Dall's porpoises could occur in the Level A harassment zone for a duration long enough to incur auditory injury during each month of impact pile driving (42 days of pile driving). Using the monthly equation above, NMFS proposes to authorize 12 takes by Level A harassment of Dall's porpoises.

Harbor Porpoise

There are multiple sightings of harbor porpoises every month, and they could occur every day during the project. They typically occur in groups of one to three individuals (Dahlheim *et al.,* 2009). Up to one group of three harbor porpoises are expected to occur in the project area per day. Therefore, using the daily equation given above, NMFS proposes to authorize 321 takes by Level B harassment of harbor porpoises.

The largest Level A harassment zone for harbor porpoises extends 4,381 m from the sound source (table 7) during impact pile driving. Hoonah would be required to implement shutdowns during all pile driving activities. However, during impact pile driving of the 20-in fender piles, 16-in fender piles, sheet piles, and 36-in piles, the Level A harassment zones for the harbor porpoise extend beyond the shutdown zone, and NMFS anticipates that Level A harassment could occur. Hoonah expects, and NMFS concurs, that up to one group of two harbor porpoises could be present in the Level A harassment zone for each day of impact pile driving (42 days of pile driving). Using the daily equation given above, NMFS proposes to authorize 84 takes by Level A harassment of harbor porpoises.

Harbor Seal

There are a multiple sightings of harbor seals every month, and they could occur every day during the project. They typically occur in groups of one to four individuals (Jefferson *et al.,* 2019). Up to one group of two harbor seals are expected to occur in the project area per day. Therefore, using the daily equation given above, NMFS proposes to authorize 214 takes by Level B harassment of harbor seals. Additionally there is a harbor seal haulout located three km (1.9 mi) from the project site where harbor seals congregate in larger numbers. Hoonah estimated, and NMFS concurs that up to 1 group of 20 harbor seals could be taken by Level B harassment every month that the Level B harassment zone is larger than 2,000 m (43 days of pile driving). Therefore, using the monthly equation given above, NMFS proposes to authorize an additional 29 takes by Level B harassment of harbor seals. Cumulatively, NMFS proposes to authorize 243 takes by Level B harassment of harbor seals.

The largest Level A harassment zone for harbor seals extends 2,515 m from the sound source (table 7) during impact pile driving. Hoonah would be required to implement shutdowns during all pile driving activities. However, during impact pile driving of the 20-in fender piles, 16-in fender piles, sheet piles, and 36-in piles, the Level A harassment zones for the harbor porpoise extend beyond the shutdown zone, and NMFS anticipates that Level A harassment could occur. Hoonah expects, and NMFS concurs, that up to one harbor seal could be present in the Level A harassment zone for each day of impact pile driving (42 days of pile driving). Using the equation given above, the calculated estimated take by Level A harassment for harbor seals would be 42.

Steller Sea Lion

There are a multiple sightings of Steller sea lions every month, and they could occur every day during the project. They typically occur in groups of one to four individuals (NMFS 2023f). Up to one group of four Steller sea lions is expected to occur in the project area per day. Therefore, using the daily equation given above, NMFS proposes to authorize 428 takes by Level B harassment of Steller sea lions. Both the Eastern DPS and Western DPS of Steller sea lions occur in the project area. NMFS estimates that the majority of Steller sea lions in the project area (99.6 percent) would be from the Eastern DPS and 1.4 percent would be from the Western DPS (Hastings *et al.,* 2020). Therefore, of the 428 total takes by Level B harassment, NMFS anticipates that 422 takes would be of individuals from the Eastern DPS and 6 takes of individuals from the Western DPS.

The largest Level A harassment zone for Steller sea lions extends 938 m from the sound source (table 7). All construction work would be shut down prior to a Steller sea lion entering the Level A harassment zone specific to the in-water activity underway at the time. In consideration of the proposed shutdown requirements, no take by Level A harassment is anticipated or proposed for Steller sea lions.

TABLE 8—ESTIMATED TAKE BY LEVEL A AND LEVEL B HARASSMENT, BY SPECIES AND STOCK

Common name	Stock	Stock abundance [1]	Level A harassment	Level B harassment	Total proposed take	Proposed take as percentage of stock [2]
Minke whale	Alaska	UND	0	11	11	[3] UND
Humpback whale	Hawaii DPS	11,278	0	214	214	1.9
	Mexico DPS	3,477				6.1
Killer whale	Eastern North Pacific Alaska Resident	1,920	0	72	72	3.8
	West Coast Transient	349				20.6
	Eastern North Pacific Northern Resident.	302				23.8
Pacific white-sided dolphin	North Pacific	26,880	0	153	153	0.6
Dall's porpoise	Alaska	UND	12	72	83	[4] UND
Harbor porpoise	Northern Southeast Alaska Inland Waters.	1,619	84	321	403	24.9
Harbor seal	Glacier Bay/Icy Strait	7,455	42	243	298	4.0
Steller sea lion	Western DPS	49,837	0	428	428	0.9
	Eastern DPS	36,308				1.2

[1] Stock size is Nbest according to NMFS 2023 Draft SARs, unless otherwise noted.

[2] Percent of stock reflects the combined total of take by Level B and Level A harassment (if requested). If a species has multiple stocks, NMFS conservatively assumes that all takes occur to each stock.
[3] The Alaska SAR does not have an estimated population size for the Alaska stock of minke whales due to only a portion of the stock's range being surveyed and such few whales seen during stock abundance surveys.
[4] NMFS does not have an official abundance estimate for this stock, and the minimum population estimate is considered to be unknown (Young *et al.,* 2023). See Small Numbers for additional discussion.

Proposed Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks, and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, NMFS considers two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned); and

(2) The practicability of the measures for applicant implementation, which may consider such things as cost, and impact on operations.

The mitigation measures described in the following paragraphs would apply to the Hoonah's in-water construction activities.

Shutdown Zones and Monitoring

Hoonah must establish shutdown zones for all pile driving activities. The purpose of a shutdown zone is generally to define an area within which shutdown of the activity would occur upon sighting of a marine animal (or in anticipation of an animal entering the defined area). Shutdown zones vary based on the activity type and duration and marine mammal hearing group, as shown in table 9. A minimum shutdown zone of 10 m would be required for all in-water construction activities to avoid physical interaction with marine mammals. Marine mammal monitoring would be conducted during all pile driving activities to ensure that shutdowns occur, as required. Proposed shutdown zones for each activity type are shown in table 9.

Prior to pile driving, shutdown zones would be established based on zones represented in table 9. Observers would survey the shutdown zones for at least 30 minutes before pile driving activities start. If marine mammals are observed within the shutdown zone, pile driving and tension anchoring will be delayed until the animal has moved out of the shutdown zone, either verified by an observer or by waiting until 15 minutes has elapsed without a sighting of small cetaceans, delphinids, and pinnipeds; or 30 minutes has elapsed without a sighting of a large cetacean. If a marine mammal approaches or enters the shutdown zone during pile driving or tension anchoring, the activity would be halted. If a species for which authorization has not been granted, or a species which has been granted but the authorized takes are met, is observed approaching or within the Level B harassment zone during pile driving or tension anchoring, the activity would be halted. Pile driving may resume after the animal has moved out of and is moving away from the shutdown zone (or Level B harassment zone for which authorization has not been granted, or a species which has been granted but the authorized takes are met) or after at least 15 minutes has passed since the last observation of the animal.

All marine mammals would be monitored in the Level B harassment zones and throughout the area as far as visual monitoring can take place. If a marine mammal enters the Level B harassment zone, in-water activities would continue and PSOs would document the animal's presence within the estimated harassment zone.

TABLE 9—SHUTDOWN AND LEVEL B HARASSMENT ZONES BY ACTIVITY

Activity	Minimum shutdown zone (m)					Level B harassment zone (m)
	LF-cetaceans	HF-cetaceans	VHF-cetaceans	Phocids	Otariids	
Vibratory Pile Driving						
Temporary 24-in steel pipe piles	20	10	15	25	10	7,360
20-in steel fender piles						
Steel sheet piles	35	15	25	40	15	4,645
16-in steel fender piles	10	10	10	10	10	2,155
H-piles	10	10	10	10	10	1,000
Wye piles						
X piles						
36-in steel pipe pile	35	15	30	45	15	11,660
36-in steel batter pile						
Impact Pile Driving						
20-in steel fender piles	590	75	200	200	195	1,000
Steel sheet piles	1,310	170	200	200	435	
16-in steel fender piles	330	42	200	200	110	465
H-piles	155	20	200	140	55	345
Wye piles	75	10	115	70	25	
X piles	50	10	75	45	20	

TABLE 9—SHUTDOWN AND LEVEL B HARASSMENT ZONES BY ACTIVITY—Continued

Activity	Minimum shutdown zone (m)					Level B harassment zone (m)
	LF-cetaceans	HF-cetaceans	VHF-cetaceans	Phocids	Otariids	
36-in steel pipe pile	1,785	230	200	200	595	1,5890
36-in steel batter pile	2,835	365	200	200	940	.....
Tension Anchoring						
6–8 in anchor hole	90	15	140	80	30	2,515

Protected Species Observers

The placement of Protected Species Observers (PSO) during all pile driving activities (described in the Proposed Monitoring and Reporting section) would ensure that the entire shutdown zone is visible. Should environmental conditions deteriorate such that the entire shutdown zone would not be visible (*e.g.,* fog, heavy rain), pile driving would be delayed until the PSO is confident marine mammals within the shutdown zone could be detected.

PSOs would monitor the full shutdown zones and as much of the Level B harassment zones as possible. Monitoring enables observers to be aware of and communicate the presence of marine mammals in the project areas outside the shutdown zones and thus prepare for a potential cessation of activity should the animal enter the shutdown zone.

Pre- and Post-Activity Monitoring

Monitoring must take place from 30 minutes prior to initiation of pile driving activities (*i.e.,* pre-clearance monitoring) through 30 minutes post-completion of pile driving. Prior to the start of daily in-water construction activity, or whenever a break in pile driving of 30 minutes or longer occurs, PSOs would observe the shutdown and monitoring zones for a period of 30 minutes. The shutdown zone would be considered cleared when a marine mammal has not been observed within the zone for a 30-minute period. If a marine mammal is observed within the shutdown zones, pile driving activity would be delayed or halted. If work ceases for more than 30 minutes, the pre-activity monitoring of the shutdown zones would commence. A determination that the shutdown zone is clear must be made during a period of good visibility (*i.e.,* the entire shutdown zone and surrounding waters must be visible to the naked eye).

Soft Start

Soft-start procedures provide additional protection to marine mammals by providing warning and/or giving marine mammals a chance to leave the area prior to the impact hammer operating at full capacity. Hoonah must implement soft start techniques when impact pile driving. Soft start requires contractors to conduct an initial set of three strikes at reduced energy, followed by a 30-second waiting period, then two subsequent three-strike sets before initiating continuous driving. Soft start will be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of 30 minutes or longer.

Based on our evaluation of the applicant's proposed measures, NMFS has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present while conducting the activities. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the activity; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and
- Mitigation and monitoring effectiveness.

Visual Monitoring

Marine mammal monitoring must be conducted in accordance with the Marine Mammal Monitoring and Mitigation Plan and section 5 of the IHA. Hoonah's draft Marine Mammal Monitoring and Mitigation Plan is Appendix D of the IHA application. Prior to the beginning of construction, Hoonah would submit a revised Marine Mammal Mitigation and Monitoring Plan containing additional details of monitoring locations and methodology for NMFS concurrence.

Marine mammal monitoring during pile driving and removal must be conducted by NMFS-approved PSOs in a manner consistent with the following:

- PSOs must be independent of the activity contractor (for example, employed by a subcontractor) and have no other assigned tasks during monitoring periods;
- At least one PSO must have prior experience performing the duties of a PSO during construction activity

pursuant to a NMFS-issued incidental take authorization;

• Other PSOs may substitute education (degree in biological science or related field) or training for prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued incidental take authorization. PSOs may also substitute Alaska native traditional knowledge for experience;

• Where a team of three or more PSOs is required, a lead observer or monitoring coordinator must be designated. The lead observer must have prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued incidental take authorization; and PSOs must be approved by NMFS prior to beginning any activity subject to this IHA.

PSOs must have the following additional qualifications:

• Ability to conduct field observations and collect data according to assigned protocols;

• Experience or training in the field identification of marine mammals, including the identification of behaviors;

• Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;

• Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates, times, and reason for implementation of mitigation (or why mitigation was not implemented when required); and marine mammal behavior; and

• Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

Between one and three PSOs will be on duty depending on the size of the Level B harassment zone. PSOs will establish monitoring locations as described in the Marine Mammal Mitigation and Monitoring Plan. Monitoring locations would be selected by the Contractor during pre-construction. PSOs would monitor for marine mammals entering the Level B harassment zones; the position(s) may vary based on construction activity and location of piles or equipment.

Monitoring would be conducted 30 minutes before, during, and 30 minutes after pile driving/removal activities. In addition, observers shall record all incidents of marine mammal occurrence, regardless of distance from activity, and shall document any behavioral reactions in concert with distance from piles being driven or removed. Pile driving/removal activities include the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than 30 minutes.

Data Collection

PSOs would use approved data forms to record the following information:

• Dates and times (beginning and end) of all marine mammal monitoring; and

• PSO locations during marine mammal monitoring.

• Construction activities occurring during each daily observation period, including how many and what type of piles were driven or removed and by what method (*i.e.,* vibratory, impact, or tension anchoring).

• Weather parameters and water conditions;

• The number of marine mammals observed, by species, relative to the pile location and if pile driving or removal was occurring at time of sighting;

• Distance and bearings of each marine mammal observed to the pile being driven or removed;

• Description of marine mammal behavior patterns, including direction of travel;

• Age and sex class, if possible, of all marine mammals observed; and

• Detailed information about implementation of any mitigation triggered (such as shutdowns and delays), a description of specific actions that ensued, and resulting behavior of the animal if any.

Reporting

A draft marine mammal monitoring report would be submitted to NMFS within 90 days after the completion of monitoring or 60 calendar days prior to the requested issuance of any subsequent IHA for construction activity at the same location, whichever comes first. It would include an overall description of work completed, a narrative regarding marine mammal sightings, and associated PSO data sheets. Specifically, the report must include:

• Dates and times (begin and end) of all marine mammal monitoring;

• Construction activities occurring during each daily observation period, including the number and type of piles driven or removed and by what method (*i.e.,* impact, vibratory, tension anchoring). The total duration of driving time must be recorded for each pile during vibratory driving and, number or strikes for each pile during impact driving, and the duration of operation of drilling and components for tension anchoring;

• PSO locations during marine mammal monitoring;

• Environmental conditions during monitoring periods (at beginning and end of PSO shift and whenever conditions change significantly), including Beaufort sea state and any other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon, and estimated observable distance;

• Upon observation of a marine mammal, the following information: (1) name of PSO who sighted the animal(s) and PSO location and activity at time of sighting; (2) time of sighting; (3) identification of the animal(s) (*e.g.,* genus/species, lowest possible taxonomic level, or unidentified), PSO confidence in identification, and the composition of the group if there is a mix of species; (4) distance and bearing of each marine mammal observed relative to the pile being driven for each sighting (if pile driving was occurring at time of sighting); (5) estimated number of animals (min/max/best estimate); (6) estimated number of animals by cohort (adults, juveniles, neonates, group composition, *etc.*); (7) animal's closest point of approach and estimated time spent within the harassment zone; and (8) description of any marine mammal behavioral observations (*e.g.,* observed behaviors such as feeding or traveling), including an assessment of behavioral responses thought to have resulted from the activity (*e.g.,* no response or changes in behavioral state such as ceasing feeding, changing direction, flushing, or breaching);

• Number of marine mammals detected within the harassment zones, by species; and

• Detailed information about any implementation of any mitigation triggered (*e.g.,* shutdowns and delays), a description of specific actions that ensued, and resulting changes in behavior of the animal(s), if any.

If no comments are received from NMFS within 30 days, the draft final report would constitute the final report. If comments are received, a final report addressing NMFS comments must be submitted within 30 days after receipt of comments.

Reporting Injured or Dead Marine Mammals

In the event that personnel involved in the construction activities discover an injured or dead marine mammal, Hoonah shall report the incident to the Office of Protected Resources (OPR), NMFS and to the Alaska regional

stranding network as soon as feasible. If the death or injury was clearly caused by the specified activity, Hoonah must immediately cease the specified activities until NMFS is able to review the circumstances of the incident and determine what, if any, additional measures are appropriate to ensure compliance with the terms of the IHA. The IHA-holder must not resume their activities until notified by NMFS. The report must include the following information:

- Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);
- Species identification (if known) or description of the animal(s) involved;
- Condition of the animal(s) (including carcass condition if the animal is dead);
- Observed behaviors of the animal(s), if alive;
- If available, photographs or video footage of the animal(s); and,
- General circumstances under which the animal was discovered.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any impacts or responses (*e.g.,* intensity, duration), the context of any impacts or responses (*e.g.,* critical reproductive time or location, foraging impacts affecting energetics), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338, September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, the majority of our analysis applies to all the species listed in table 2, given that many of the anticipated effects of this project on different marine mammal stocks are expected to be relatively similar in nature. Where there are meaningful differences between species or stocks, or groups of species, in anticipated individual responses to activities, impact of expected take on the population due to differences in population status, or impacts on habitat, they are described independently in the analysis below.

Pile driving and tension anchoring activities have the potential to disturb or displace marine mammals. Specifically, the project activities may result in take, in the form of Level A harassment (Dall's porpoise, harbor porpoise, and harbor seal) and Level B harassment from underwater sounds generated from pile driving and removal and tension anchoring. Potential takes could occur if individuals are present in the ensonified zone when these activities are underway.

The takes by Level B harassment would be due to potential behavioral disturbance and TTS. Takes by Level A harassment would be due to auditory injury. No mortality or serious injury is anticipated given the nature of the activity, even in the absence of the required mitigation. The potential for harassment is minimized through the construction method and the implementation of the proposed mitigation measures (see Proposed Mitigation section).

Take would occur within a limited, confined area (Port Fredrick) of the stocks' ranges. The intensity and duration of take by Level A harassment and Level B harassment would be minimized through use of mitigation measures described herein. Further, the amount of take proposed to be authorized is extremely small when compared to stock abundance, and the project is not anticipated to impact any known important habitat areas for any marine mammal species with the exception of a known biologically important area for humpback whales, discussed below.

Take by Level A harassment is authorized to account for the potential that an animal could enter and remain within the area between a Level A harassment zone and the shutdown zone for a duration long enough to be taken by Level A harassment. Any take by Level A harassment is expected to arise from, at most, a small degree of auditory injury because animals would need to be exposed to higher levels and/or longer duration than are expected to occur here in order to incur any more than a small degree of auditory injury. Additionally, and as noted previously, some subset of the individuals that are behaviorally harassed could also simultaneously incur some small degree of TTS for a short duration of time. Because of the small degree anticipated, though, any auditory injury or TTS potentially incurred here would not be expected to adversely impact individual fitness, let alone annual rates of recruitment or survival.

Behavioral responses of marine mammals to pile driving at the project site, if any, are expected to be mild and temporary. Marine mammals within the Level B harassment zone may not show any visual cues they are disturbed by activities or could become alert, avoid the area, leave the area, or display other mild responses that are not observable such as changes in vocalization patterns. Given the limited number of piles to be installed or extracted per day and that pile driving and removal would occur across a maximum of 107 days within the 12-month authorization period, any harassment would be temporary.

Any impacts on marine mammal prey that would occur during Hoonah's proposed activity would have, at most, short-term effects on foraging of individual marine mammals, and likely no effect on the populations of marine mammals as a whole. Indirect effects on marine mammal prey during the construction are expected to be minor, and these effects are unlikely to cause substantial effects on marine mammals at the individual level, with no expected effect on annual rates of recruitment or survival.

In addition, it is unlikely that elevated noise in a small, localized area of habitat would have any effect on the stocks' annual rates of recruitment or survival. In combination, we believe that these factors, as well as the available body of evidence from other similar activities, demonstrate that the potential effects of the specified activities will have only minor, short-term effects on individuals. The specified activities are not expected to impact rates of recruitment or survival, and will therefore not result in population-level impacts.

The waters of Glacier Bay and Icy Strait are part of the Alaska humpback whale feeding BIA (Wild *et al.,* 2023). However, underwater sound would be constrained to Port Fredrick and would be truncated by land masses in the inlet. The area of the BIA that may be affected

by the proposed project is small relative to the overall area of the BIA. The humpback whale feeding BIA is active between May and October while the proposed project is scheduled to occur between September and January, resulting in only 2 months of overlap. Additionally, pile driving associated with the project is expected to take only 107 days, further reducing the temporal overlap with the BIA. Therefore, the proposed project is not expected to have significant adverse effects on the foraging of Alaska humpback whale.

There are two known harbor seal haulouts within Port Fredrick. One of the haulouts (CE79A) is located approximately 10 km (6.25 mi) from the project site and is outside of the ensonfied zone for this action. The other (CF39A) is located approximately 3 km (2 mi) from the project site and will be ensonified during some vibratory and impact pile driving activities. Neither of these haulouts are listed as a ''key haulout,'' or a haulout with 50 or more individuals present at the time of survey (AFSC 2024). Given that these are not considered key haulouts, and the maximum of 43 days that the ensonified zone will extend over 2 km, the proposed project is not expected to have significant adverse effects on harbor seal haulout sites. No areas of specific biological importance (*e.g.,* ESA critical habitat, other BIAs, or other areas) for any other species are known to co-occur with the project area.

In summary and as described above, the following factors primarily support our preliminary determination that the impacts resulting from this activity are not expected to adversely affect any of the species or stocks through effects on annual rates of recruitment or survival:

- No serious injury or mortality is anticipated or authorized;
- For all species except Dall's porpoises, harbor porpoises, and harbor seals, no Level A harassment is anticipated or proposed for this action;
- The intensity of anticipated takes by Level B harassment is relatively low for all stocks and would not be of a duration or intensity expected to result in impacts on reproduction or survival;
- The lack of anticipated significant or long-term negative effects to marine mammal habitat;
- With the exception of the humpback whale BIA described above, no areas of specific biological importance (*e.g.,* ESA critical habitat, other BIAs, or other areas) for any other species are known to co-occur with the project area; and
- Hoonah would implement mitigation measures, such as soft-starts for impact pile driving and shutdowns to minimize the numbers of marine mammals exposed to injurious levels of sound, and to ensure that take by Level A harassment, is at most, a small degree of auditory injury.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS preliminarily finds that the total marine mammal take from the proposed activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted previously, only take of small numbers of marine mammals may be authorized under sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted number of individuals to be taken is fewer than one-third of the species or stock abundance, the take is considered to be of small numbers. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

For all stocks, except for the Alaska stock of minke whales and the Alaska stock of Dall's porpoises, whose abundance estimate is unknown, the proposed number of takes is less than one-third of the best available population abundance estimate (table 8). The numbers of animals proposed for authorization to be taken from these stocks would be considered small relative to the relevant stocks' abundances, even if each estimated taking occurred to a new individual—an extremely unlikely scenario.

Current abundance estimates of Dall's porpoises in the region are not available. the most recent estimate (83,400 individuals) does not include coastal or inland waters of southeast Alaska and is considered unreliable since it is based upon data collected more than 8 years ago (Young *et al.,* 2023). However, given the size of the most recent estimate, the 83 takes of this stock proposed for authorization clearly represents small numbers of this stock.

There is no current or historical estimate of the Alaska minke whale stock, but there are known to be over 1,000 minke whales in the Gulf of Alaska (Muto *et al.* 2018), so the 11 takes proposed for authorization is small relative to estimated survey abundance, even if each proposed take occurred to a new individual. Additionally, the range of the Alaska stock of minke whales is extensive, stretching from the Canadian Pacific coast to the Chukchi Sea, and Hoonah's proposed project area would impact a small portion of this range.

Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily finds that small numbers of marine mammals would be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

In order to issue an IHA, NMFS must find that the specified activity will not have an ''unmitigable adverse impact'' on the subsistence uses of the affected marine mammal species or stocks by Alaskan Natives. NMFS has defined ''unmitigable adverse impact'' in 50 CFR 216.103 as an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (i) Causing the marine mammals to abandon or avoid hunting areas; (ii) Directly displacing subsistence users; or (iii) Placing physical barriers between the marine mammals and the subsistence hunters; and (2) That cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

Alaska Natives have traditionally harvested subsistence resources, including marine mammals, in the Glacier Bay and Icy Strait for a millennia. Present day Hoonah is the principle village of the Huna tribe, and according to Ian Johnson, Hoonah Indian Association's Environmental Coordinator, no known marine mammal harvest takes place in the immediate HMIC area (Johnson 2024). Limited subsistence harvests of marine mammals within Port Fredrick has occurred in the past, with the most recent recorded/documented harvests of marine mammals in Hoonah in 2012. The proposed activity will take place in Port Fredrick, and no activities overlap with current subsistence hunting areas; therefore, there are no relevant subsistence uses of marine mammals adversely impacted by this action. The proposed project is not likely to

adversely impact the availability of any marine mammal species or stocks that are commonly used for subsistence purposes or to impact subsistence harvest of marine mammals in the region.

Based on the description of the specified activity, the measures described to minimize adverse effects on the availability of marine mammals for subsistence purposes, and the proposed mitigation and monitoring measures, NMFS has preliminarily determined that there will not be an unmitigable adverse impact on subsistence uses from Hoonah's proposed activities.

Endangered Species Act

Section 7(a)(2) of the ESA of 1973 (16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species, in this case with the Alaska Regional Office.

NMFS is proposing to authorize take of humpback whales (Mexico DPS) and Steller sea lions (western DPS), which are listed under the ESA. The Permits and Conservation Division has requested initiation of section 7 consultation with the Alaska Region for the issuance of this IHA. NMFS will conclude the ESA consultation prior to reaching a determination regarding the proposed issuance of the authorization.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to Hoonah for conducting the Hoonah Cargo Dock Project in Hoonah, Alaska from September 1, 2025 through August 31, 2026, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. A draft of the proposed IHA can be found at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities.*

Request for Public Comments

We request comment on our analyses, the proposed authorization, and any other aspect of this notice of proposed IHA for the proposed construction project. We also request comment on the potential renewal of this proposed IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform decisions on the request for this IHA or a subsequent renewal IHA.

On a case-by-case basis, NMFS may issue a one-time, 1-year renewal IHA following notice to the public providing an additional 15 days for public comments when (1) up to another year of identical or nearly identical activities as described in the Description of Proposed Activity section of this notice is planned or (2) the activities as described in the Description of Proposed Activity section of this notice would not be completed by the time the IHA expires and a renewal would allow for completion of the activities beyond that described in the *Dates and Duration* section of this notice, provided all of the following conditions are met:

- A request for renewal is received no later than 60 days prior to the needed renewal IHA effective date (recognizing that the renewal IHA expiration date cannot extend beyond 1 year from expiration of the initial IHA);
- The request for renewal must include the following:

(1) An explanation that the activities to be conducted under the requested renewal IHA are identical to the activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (*e.g.,* reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take); and

(2) A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized; and

- Upon review of the request for renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

Dated: January 2, 2025.

Catherine Marzin,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2025–00014 Filed 1–6–25; 8:45 am]

BILLING CODE 3510–22–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 10:30 a.m. EST, Friday, January 10, 2025.

PLACE: Virtual meeting.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Enforcement and examinations matters. In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at *https://www.cftc.gov/.*

CONTACT PERSON FOR MORE INFORMATION: Christopher Kirkpatrick, 202–418–5964.

(Authority: 5 U.S.C. 552b.)

Dated: January 3, 2025.

Christopher Kirkpatrick,

Secretary of the Commission.

[FR Doc. 2025–00222 Filed 1–3–25; 4:15 pm]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 9:30 a.m. EST, Friday, January 10, 2025.

PLACE: Virtual meeting.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Matters relating to the CFTC's bargaining position and related issues concerning ongoing negotiations over CFTC employee compensation and benefits. In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at *https://www.cftc.gov/.*

CONTACT PERSON FOR MORE INFORMATION: Christopher Kirkpatrick, 202–418–5964.

(Authority: 5 U.S.C. 552b.)

Dated: January 3, 2025.

Christopher Kirkpatrick,

Secretary of the Commission.

[FR Doc. 2025–00221 Filed 1–3–25; 4:15 pm]

BILLING CODE 6351–01–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Notice of Record of Decision for the Environmental Impact Statement Air National Guard F–15EX Eagle II & F–35A Lightning II Operational Beddowns

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Notice of Availability of Record of Decision.

SUMMARY: On December 19, 2024, the Department of the Air Force (DAF) signed the Record of Decision (ROD) for the Air National Guard F–15EX Eagle II & F–35A Lightning II Operational Beddowns Environmental Impact Statement.

ADDRESSES: Mr. Devin Scherer (NGB/A4), Air National Guard Readiness Center; 3501 Fetchet Avenue; Joint Base Andrews, MD 20762; *ngb.a4.a4a.nepa.comments.org@us.af.mil*; (240) 612–8422.

SUPPLEMENTARY INFORMATION: The DAF has decided to replace the aging F–15C/D fighter aircraft at the 104th Fighter Wing (104 FW) at Westfield-Barnes Regional Airport, Westfield, Massachusetts; 144th Fighter Wing (144 FW) at Fresno Yosemite International Airport, Fresno, California; and the 159th Fighter Wing (159 FW) at Naval Air Station Joint Reserve Base New Orleans, Belle Chasse, Louisiana. At the 104 FW, 18 F–15C aircraft will be replaced with up to 21 F–35A aircraft. At the 144 FW, 18 F–15C aircraft will be replaced with up to 21 F–15EX aircraft. At the 159 FW 18 F–15C/D aircraft will be replaced with up to 21 F–15EX aircraft.

The DAF decision documented in the ROD was based on matters discussed in the Final Environmental Impact Statement, inputs from the public and regulatory agencies, and other relevant factors. The Final Environmental Impact Statement was made available to the public on November 15, 2024 through a Notice of Availability in the **Federal Register** (89 FR 90280) with a waiting period that ended on December 16, 2024.

Authority: This Notice of Availability is published pursuant to the regulations (40 CFR part 1506.6) implementing the provisions of the National Environmental Policy Act (42 U.S.C. 4321, *et seq.*) and the Air Force's Environmental Impact Analysis Process (32 CFR parts 989.21(b) and 989.24(b)(7)).

Tommy W. Lee,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2025–00069 Filed 1–6–25; 8:45 am]

BILLING CODE 3911–44–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Notice of Availability of Designation of Chinese Military Companies

AGENCY: Office of the Under Secretary of Defense (Acquisition and Sustainment), Department of Defense.

ACTION: Notice of Chinese military companies operating in the United States.

SUMMARY: The Deputy Secretary of Defense has determined that the entities listed in the **SUPPLEMENTARY INFORMATION** section of this notice qualify as ''Chinese military companies'' in accordance with the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021.

FOR FURTHER INFORMATION CONTACT: Mr. Devante Brown (GIES), (703) 695–8545.

SUPPLEMENTARY INFORMATION: Section 1260H of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (Pub. L. 116–283) requires the Secretary of Defense to identify and publish a list of ''Chinese military companies'' annually until December 31, 2030. Paragraph (b)(2) of this section requires the Secretary of Defense to publish the unclassified portion of such list in the **Federal Register** (FR).

The Deputy Secretary of Defense has determined that the following entities qualify as ''Chinese military companies'' in accordance with Section 1260H[1]:

360 Security Technology Inc. (Qihoo 360).
Aerospace CH UAV Co., Ltd (CH UAV)
Autel Robotics Co., Ltd.
Aviation Industry Corporation of China Ltd. (AVIC)
AVIC Aerospace Systems Co., Ltd.
AVIC Airborne Systems Co., Ltd. (formerly China Avionics Systems Co., Ltd.)
AVIC Asset Management Corporation Ltd.
AVIC Aviation High-Technology Company Limited (AVIC Aviation Hi-Tech)
AVIC Electromechanical Systems Co. Ltd.
AVIC Heavy Machinery Company Limited (AVIC Heavy Machinery)
AVIC JONHON Optronic Technology Co., Ltd. (AVIC Jonhon)
AVIC Shenyang Aircraft Company Limited (AVIC Shenyang)
AVIC Xi'an Aircraft Industry Group Company Ltd. (AVIC Xi'an)
Changhe Aircraft Industries (Group) Co., Ltd.
Jiangxi Hongdu Aviation Industry Co., Ltd. (Hongdu Aviation)
Shenyang Aircraft Design Institute
Xi'an Aircraft Industry Group Co., Ltd.
Zhonghang Electronic Measuring Instruments Company Limited (ZEMIC)
Baicells Technologies Co., Ltd.
Beijing Zhidao Chuangyu Information Technology Co., Ltd. (Knownsec)
BGI Group
BGI Genomics Co., Ltd. (BGI)
Forensic Genomics International (FGI)
MGI Tech Co., Ltd. (MGI)
ChangXin Memory Technologies, Inc. (CXMT)
Chengdu JOUAV Automation Tech Co., Ltd. (JOUAV)
Chengdu M&S Electronics Technology Co., Ltd. (M&S Electronics)
China Aerospace Science and Industry Corporation Limited (CASIC)
Addsino Co., Ltd.
Aerospace Precision Products Co., Ltd.
Aerosun Corporation (Aerosun)
Aisino Corporation
China Aerospace Automotive Co., Ltd.
China Cargo Airlines Co., Ltd.
China Communications Construction Group (Limited) (CCCG)
China Airport Construction Group Corporation
China Communications Construction Company Limited (CCCC)
China Communications Constructions USA, Inc.
China Traffic Construction USA, Inc.
John Holland Group Pty Ltd.
John Holland Services Pty Ltd.
China Construction Technology Co., Ltd. (CCTC)
China COSCO SHIPPING Corporation Limited (COSCO SHIPPING)
COSCO SHIPPING (North America) Inc.
COSCO SHIPPING Finance Co., Ltd.
China Electronics Corporation (CEC)
China International Information Services Ltd.
China Electronics Technology Group Corporation (CETC)
Anhui Sun Create Electronics Co., Ltd.
Cheng Du Westone Information Industry Co., Ltd.
GLARUN Technology Co., Ltd.

[1] Hesai Technology Co., Ltd. was previously identified as and remains a Chinese military company operating in the United States in accordance with Section 1260H of the William M. (''Mac'') Thornberry National Defense Authorization Act for Fiscal Year 2021 (Pub. L. 116–283) as reported in 89 FR 86230 (October 29, 2024).

Guangzhou GCI Science & Technology Co., Ltd.
Hangzhou Hikvision Digital Technology Co., Ltd. (Hikvision)
Phoenix Optics Company Limited
Shanghai East China Computer Co., Ltd.
Taiji Computer Co., Ltd.
China General Nuclear Power Corporation (CGN)
China International Marine Containers (Group) Co., Ltd. (CIMC)
China Mobile Communications Group Co., Ltd. (China Mobile Comm)
China Mobile Limited (China Mobile)
China National Chemical Corporation Ltd. (ChemChina)
China National Chemical Engineering Group Corporation (CNCEC)
China National Chemical Engineering Co., Ltd.
China National Nuclear Corporation (CNNC)
China National Offshore Oil Corporation (CNOOC)
CNOOC China Limited (CNOOC China Ltd.)
CNOOC International Trading Co., Ltd. (CNOOC International Trading)
China North Industries Group Corporation Limited (Norinco Group)
Harbin First Machinery Group Ltd.
Inner Mongolia First Machinery Group Co., Ltd. (Inner Mongolia)
China Shipbuilding Trading Co., Ltd. (CSTC)
China South Industries Group Corporation (CSGC)
Costar Group Co., Ltd. (Costar)
Heilongjiang Northern Tools Co., Ltd.
China SpaceSat Co., Ltd. (China SpaceSat)
Oriental Blue Sky Titanium Technology Co., Ltd.
Xi'an Aerospace Tianhua Data Technology Co., Ltd.
China State Construction Engineering Corporation Limited (CSCEC)
China Construction America, Inc.
China State Shipbuilding Corporation Limited (CSSC)
China Telecom Group Co., Ltd. (China Telecom)
China Telecom Corporation Limited
China Three Gorges Corporation (CTG)
China United Network Communications Group Co., Ltd. (China Unicom)
China Unicom (BVI) Co., Ltd.
China Unicom (Hong Kong) Limited (China Unicom HK)
China Unicom Group (BVI) Co., Ltd.
China United Network Communications Co., Ltd.
CloudWalk Technology Co., Ltd. (CloudWalk)
Commercial Aircraft Corporation of China Limited (COMAC)
Beijing Aeronautical Science & Technology Research Institute (Beijing Research Center)
COMAC America Corporation (CAC)
Shanghai Aircraft Manufacturing Co., Ltd. (Assembly Manufacturing Center)
Contemporary Amperex Technology Co., Ltd. (CATL)
CRRC Corporation Limited (CRRC)
CSSC Offshore & Marine Engineering (Group) Company Limited (COMEC)
Guangzhou Wenchong Shipyard Co., Ltd.
Huacheng (Tianjin) Ship Leasing Co., Ltd.
Dawning Information Industry Co., Ltd. (Sugon)
Global Tone Communication Technology Co., Ltd. (GTCOM)
GTCOM Technology Corporation (GTCOM–US)
Guizhou Aviation Technical Development Co., Ltd. (Guizhou Aviation Tech)
Huawei Investment & Holding Co., Ltd. (Huawei Holding)
Huawei Technologies Co., Ltd. (Huawei)
Inspur Group Co., Ltd. (Inspur)
NetPosa Technologies, Ltd. (NetPosa)
Origincell Technology Co., Ltd.
Quectel Wireless Solutions Co., Ltd.
SDIC Intelligence (Xiamen) Information Co., Ltd.
Xiamen Meiya Zhongmin Electronic Technology Co., Ltd.
Semiconductor Manufacturing International Corporation (SMIC)
Better Way Enterprises Limited
China IC Capital Co., Ltd.
Magnificent Tower Limited
Semiconductor Manufacturing International (Beijing) Corporation (SMIC Beijing)
Semiconductor Manufacturing International (Shenzhen) Corporation (SMIC Shenzhen)
Semiconductor Manufacturing International (Tianjin) Corporation (SMIC Tianjin]
Semiconductor Manufacturing North China (Beijing) Corporation
Semiconductor Manufacturing South China Corporation (SMIC South China)
SilTech Semiconductor Corporation
SMIC Holdings Limited (SMIC Holdings)
SMIC Semiconductor Manufacturing (Shanghai) Co., Ltd (SMIC Shanghai)
SMIC, Americas
SenseTime Group, Inc.
Shanghai Yitu Network Technology Co., Ltd. (Yitu)
Shenzhen DJI Innovation Technology Co., Ltd. (DJI)
Shenzhen Dajiang Baiwang Technology Co., Ltd.
Sinotrans & CSC Holdings Co., Ltd.
Tencent Holdings Limited
Wuhan Geosun Navigation Technology Co., Ltd. (Geosun)
Yangtze Memory Technologies Co., Ltd. (YMTC)
Zhejiang Dahua Technology Co., Ltd. (Dahua)
Chengdu Dahua Wisdom Information Technology Co., Ltd.
* Subsidiaries Listed with Parent Companies

The Deputy Secretary of Defense has determined that the following previously listed entities should be removed from the most recent Section 1260H List announced on January 31, 2024:

Beijing Megvii Technology Co., Ltd. (Megvii)
China Marine Information Electronics Company Limited (China Marine Info Elec)
China Railway Construction Corporation Limited (CRCC)
China State Construction Group Co.
China Telecommunications Corporation
ShenZhen Consys Science & Technology Co., Ltd. (Consys)

Reconsideration Process

Entities that are included on the 1260H List may request reconsideration of this decision. Requests for reconsideration should include:

1. The listed entity's name and mailing address (including email address) and an authorized representative's name and mailing address (including email address) and

2. A statement indicating the entity's intent to request reconsideration of the Department's determination, including a detailed description with supporting evidence of why the listed entity should be removed from the 1260H List.

The request for removal may also include additional information such as arguments and evidence that establishes that an insufficient basis exists for the listing or that the circumstances resulting in the listing no longer apply.

Requests for reconsideration must be emailed to *osd.pentagon.ousd-a-s.list.1260h-list@mail.mil*.

Dated: January 2, 2025.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2025–00070 Filed 1–6–25; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Native American Career and Technical Education Program (NACTEP)

AGENCY: Office of Career, Technical, and Adult Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting

applications for new awards for fiscal year (FY) 2025 for the Native American Career and Technical Education Program (NACTEP).

DATES:

Applications Available: January 7, 2025.

Deadline for Notice of Intent to Apply: Applicants are strongly encouraged, but not required, to submit a notice of intent to apply by February 6, 2025.

Deadline for Transmittal of Applications: March 10, 2025.

Deadline for Intergovernmental Review: May 7, 2025.

Pre-Application Webinar Information: For information about a pre-application webinar or potential future webinars, visit the Perkins Collaborative Resource Network (PCRN) at *http://cte.ed.gov/.*

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 7, 2022 (87 FR 75045), and available at *www.federalregister.gov/documents/2022/12/07/2022-26554/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs.*

FOR FURTHER INFORMATION CONTACT: Patti Beltram, Ed.D., U.S. Department of Education, 400 Maryland Avenue SW, Room 4A115, Washington, DC 20202. Telephone: (202) 987–1370. Email: *NACTEP@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:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: NACTEP provides grants to improve career and technical education (CTE) programs that are consistent with the purposes of the Carl D. Perkins Career and Technical Education Act of 2006 (the Act or Perkins V), and that benefit Native Americans and Alaska Natives.

Assistance Listing Number: 84.101A.

OMB Control Number: 1894–0006.

Background: This notice invites applications for a NACTEP competition that implements section 116 of the Act. Section 116 of the Act authorizes the Secretary of Education (Secretary) to award grants to, or enter into cooperative agreements or contracts with, Indian Tribes, Tribal organizations, and Alaska Native entities to operate CTE projects that improve CTE for Native American and Alaska Native students.

Under section 116 of the Act, a Bureau-funded school (as defined in this notice) is not eligible to apply for NACTEP funds for its general education program. Its application must be to carry out a supplemental CTE program in its secondary school.

Tribal Consultation: In accordance with the Department's commitment to engage in regular and meaningful consultation and collaboration with Indian Tribes, the Office of Career, Technical, and Adult Education (OCTAE) and the White House Initiative on American Indian and Alaska Native Education conducted a Tribal Consultation regarding NACTEP on July 23, 2024. Consistent with its trust responsibility to Tribes and its Tribal Consultation Policy, the Department sought views from elected officials of federally recognized Tribes as well as stakeholders and educators from the Tribal community to inform the Department's policy decisions related to potential grant competition priorities, the timing of the program's project performance period, funding available under the Perkins V state formula grant, and grant consolidation under the provisions of Public Law 115–93, the Indian Employment, Training and Related Services Consolidation Act of 2017 (25 U.S.C. 3401 *et seq.*), which amended the Indian Employment and Related Services Demonstration Act of 1992, Public Law 102–477 (related to which a Tribe may submit a ''477 plan''). The consultation also included discussion of student stipends, direct assistance to students, and the independent evaluation requirement established by the notice of final requirements, definitions, and selection criteria for this program (Notice of Final Requirements), published in the **Federal Register** on February 26, 2013 (78 FR 12955). Representatives from participating Tribal nations expressed the need for flexibility in the program in order to address locally identified needs, noting continued interest in CTE programs that support careers in the trades, including plumbing, electrical, carpentry, and construction. Other Tribal stakeholders mentioned the need for CTE programs that prepare students for careers in cybersecurity and computer science, healthcare, math, early childhood education, and natural resource management. A few participants referenced the need for culturally competent programming and culturally responsive models that support indigenized curricula. Tribal leaders expressed a need for continued direct assistance to students under NACTEP to allow the use of funds for childcare, transportation, and technology in order to support families through responsive programming. Tribal participants expressed an interest in utilizing NACTEP funding to strengthen cross-agency coordination to better support the transition between secondary and postsecondary education.

Executive Order 14112:

Executive Order 14112, ''Reforming Federal Funding and Support for Tribal Nations to Better Embrace Our Trust Responsibilities and Promote the Next Era of Tribal Self-Determination'',[1] issued by President Joseph R. Biden on December 6, 2023, calls for Federal programs to provide Tribal Nations with the flexibility to improve economic growth, address the specific needs of their communities, and realize their vision for their future and for agencies to improve our Nation-to-Nation relationships by reducing administrative burdens and by administering funding in a manner that provides Tribal Nations with the greatest possible autonomy to address the specific needs of their people. Additionally, Executive Order 14112 requires Federal agencies to reduce barriers Tribal Nations face in accessing the Federal funding and resources for which they are eligible and that they need to help grow their economies and provide their citizens with important services. This NACTEP competition serves the goals of both the Executive Order and Perkins V. It provides an opportunity to reduce potential funding barriers for CTE programs by reducing the number of program and application requirements, which makes it easier for applicants and increases flexibility for programs that address locally-identified needs.

Priorities: This competition has one absolute priority. The Absolute Priority is from section 116 of the Act.

Absolute Priority: For FY 2025, and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet the Absolute Priority.

The priority is:

Authorized Program.

To meet this priority, applicants must propose and carry out a career and

[1] Executive Office of the President, Executive Order 14112 (December 6, 2023), Reforming Federal Funding and Support for Tribal Nations to Better Embrace Our Trust Responsibilities and Promote the Next Era of Tribal Self-Determination, 88 FR 86021. Retrieved from: *https://www.federalregister.gov/documents/2023/12/11/2023-27318/reforming-federal-funding-and-support-for-tribal-nations-to-better-embrace-our-trust.*

technical education program consistent with the Carl D. Perkins Act of 2006. (20 U.S.C. 2302(5))

Note: If an applicant with an open NACTEP grant receives a grant under this competition, they must demonstrate that the activities and objectives of the grant will not duplicate or overlap with the expenses, activities, and objectives of other open grants with the same or similar activities and objectives. (2 CFR 200.403 and 200.404)

Requirements:

This notice includes two application and three program requirements that are based on statutory requirements or the Notice of Final Requirements. The source is noted after each requirement.

The application requirements are:

(1) *Demonstration of Eligibility.* (a) An eligible applicant (as determined by the Act) must include documentation in its application showing that it and, if appropriate, its consortium members are eligible to apply.

(b) As defined in the Indian Self-Determination and Education Assistance Act (ISDEAA) (25 U.S.C. 5304(l)), the term ''Tribal organization'' means the recognized governing body of any Indian Tribe; any legally established organization of Indians which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Indians in all phases of its activities: provided, that in any case where a contract is let or grant made to an organization to perform services benefiting more than one Indian Tribe, the approval of each such Indian Tribe shall be a prerequisite to the letting or making of such contract or grant. In accordance with this statutory definition, any Tribal organization proposing to provide NACTEP services for the benefit of more than one Indian Tribe must first obtain the approval of each Indian Tribe it proposes to serve and must submit documentation of such approval with its NACTEP application and that documentation of Tribal approval is a prerequisite to the awarding of a NACTEP grant to any Tribal organization proposing to serve more than one Indian Tribe. (Notice of Final Requirements).

(2) *Career and technical education agreement.* Any applicant that is not proposing to provide CTE directly to its students and proposes instead to use NACTEP funds to pay one or more qualified educational entities to provide education to its students must include with its application a written career and technical education agreement between the applicant and that entity. This written agreement must describe the commitment between the applicant and each educational entity and must include, at a minimum, a statement of the responsibilities of the applicant and the entity. The agreement must be signed by the appropriate individuals on behalf of each party, such as the authorizing official or president of a Tribe or Tribal organization, a college president, or a college dean. (Notice of Final Requirements).

The program requirements are:

Requirement 1—Authorized Use of NACTEP Funds:

Section 116(c) of the Act requires that funds awarded under NACTEP be used to carry out ''career and technical education programs'' (20 U.S.C. 2326(c), as the term ''career and technical education'' is defined by the Act as amended by the Strengthening Career and Technical Education for the 21st Century Act (20 U.S.C. 2302(5)). Grantees may use funds awarded under NACTEP to—

(1) Provide preparatory, refresher, and remedial education services that are designed to enable students to achieve success in career and technical education programs or programs of study.

(2) Provide stipends to students who are enrolled in career and technical education programs and who have acute economic needs which cannot be met through work-study programs. Stipends shall not exceed reasonable amounts as prescribed by the Secretary.

Note: As noted in the Eligibility section below, and consistent with section 116(b)(1) of Perkins V, a Bureau-funded secondary school is not eligible to directly apply for NACTEP funds for its general education secondary school program.

Note: Each organization, Tribe, or entity receiving assistance under this section may consolidate such assistance in a 477 plan in accordance with the provisions of the Indian Employment, Training and Related Services Demonstration Act of 1992 (25 U.S.C. 3401 *et seq.*) 20 U.S.C. 23236(f). Consistent with that statute, any request to consolidate NACTEP funds into a 477 plan must be made separately to the U.S. Department of Interior. Please see section IV on Application Submission for more information.

Requirement 2—Direct Assistance to Students:

A grantee may provide direct assistance to students if the following conditions are met:

(1) The recipient of the direct assistance is an individual who is a member of a special population and who is participating in the grantee's NACTEP project.

(2) The direct assistance is needed to address barriers to the individual's successful participation in that project.

(3) The direct assistance is part of a broader, more generally focused program or activity to address the needs of an individual who is a member of a special population.

Note: Direct assistance to individuals who are members of special populations is not, by itself, a ''program or activity for special populations''.

(4) The grant funds used for direct assistance must be expended to supplement, and not supplant, assistance that is otherwise available from non-Federal sources. (20 U.S.C. 2391(a)). For example, generally, a postsecondary educational institution could not use NACTEP funds to provide child care for single parents if non-Federal funds previously were made available for this purpose, or if non-Federal funds are used to provide child care services for single parents participating in non-CTE programs and these services otherwise would have been available to CTE students in the absence of NACTEP funds.

(5) In determining how much of the NACTEP grant funds it will use for direct assistance to an eligible student, a grantee must consider whether the specific services to be provided are a reasonable and necessary cost of providing CTE programs for special populations. However, the Assistant Secretary does not envision a circumstance in which it would be a reasonable and necessary expenditure of NACTEP project funds for a grantee to use a majority of a project's budget to pay direct assistance to students, in lieu of providing the students served by the project with CTE. (Notice of Final Requirements).

Requirement 3—ISDEAA Statutory Hiring Preference:

(1) Awards that are primarily for the benefit of Indians are subject to the provisions of section 7(b) of the Indian Self-Determination and Education Assistance Act (ISDEAA) (Pub. L. 93–638). That section requires that, to the greatest extent feasible, a grantee—

(i) Give to Indians preferences and opportunities for training and employment in connection with the administration of the grant; and

(ii) Give to Indian organizations and to Indian-owned economic enterprises, as defined in section 3 of the Indian Financing Act of 1974 (25 U.S.C. 1452(e)), preference in the award of subcontracts and subgrants in connection with the administration of the grant. (25 U.S.C. 5307(b))

(2) For purposes of Requirement 3, an Indian is a member of any federally recognized Indian Tribe. (25 U.S.C. 5304(d)).

Definitions: These definitions are from the Act or the Notice of Final Requirements. The source of each definition is noted after the definition.

Acute economic need means an income that is at or below the national poverty level according to the latest available data from the U.S. Department of Commerce or the U.S. Department of Health and Human Services Poverty Guidelines. (Notice of Final Requirements).

Alaska Native or Native means a citizen of the United States who is a person of one-fourth degree or more Alaska Indian (including Tsimshian Indians not enrolled in the Metlaktla Indian Community) [2] Eskimo, or Aleut blood, or a combination thereof. The term includes—

(a) Any Native, as so defined, either or both of whose adoptive parents are not Natives; and

(b) In the absence of proof of a minimum blood quantum, any citizen of the United States who is regarded as an Alaska Native by the Native village or Native group of which he or she claims to be a member and whose father or mother is (or, if deceased, was) regarded as Native by any village or group. Any decision of the Secretary of the Interior regarding eligibility for enrollment will be final. (20 U.S.C. 2326(a)(1); 43 U.S.C. 1602(b)).

Alaska Native group means any Tribe, band, clan, village, community, or village association of Natives in Alaska composed of less than twenty-five Natives, who comprise a majority of the residents of the locality. (43 U.S.C. 1602(d)).

Alaska Native village means any Tribe, band, clan, group, village, community, or association in Alaska listed in sections 1610 and 1615 of the Alaska Native Claims Settlement Act, or that meets the requirements of chapter 33 of the Alaska Native Claims Settlement Act, and that the Secretary of the Interior determines was, on the 1970 census enumeration date (as shown by the census or other evidence satisfactory to the Secretary of the Interior, who shall make findings of fact in each instance), composed of twenty-five or more Natives. (43 U.S.C. 1602(c)).

Alaska regional corporation means an Alaska Native regional corporation established under the laws of the State of Alaska in accordance with the provisions of chapter 33 of the Alaska Native Claims Settlement Act. (43 U.S.C. 1602(g)).

Alaska village corporation means an Alaska Native village corporation organized under the laws of the State of Alaska as a business for profit or nonprofit corporation to hold, invest, manage and/or distribute lands, property, funds, and other rights and assets for and on behalf of an Alaska Native village, in accordance with the terms of chapter 33 of the Alaska Native Claims Settlement Act. (43 U.S.C. 1602(j)).

Bureau means the Bureau of Indian Affairs of the U.S. Department of the Interior. (25 U.S.C. 2021(2)).

Bureau-funded school means—

(a) A Bureau-operated elementary or secondary day or boarding school or Bureau-operated dormitory for students attending a school other than a Bureau school. (25 U.S.C. 2021(3) and (4));

(b) An elementary school, secondary school, or dormitory that receives financial assistance for its operation under a contract, grant, or agreement with the Bureau under section 102, 103(a), or 208 of the ISDEAA (25 U.S.C. 5321, 5322(a), or 5355) or under the Tribally Controlled Schools Act of 1988 (25 U.S.C. 2504 *et seq.*). (25 U.S.C. 2021(3) and (6)); or

(c) A school for which assistance is provided under the Tribally Controlled Schools Act of 1988 (25 U.S.C. 2501 *et seq.*). (25 U.S.C. 2021(3)).

Career and technical education (CTE) means organized educational activities that—

(a) Offer a sequence of courses that—

(1) Provides individuals with rigorous academic content and relevant technical knowledge and skills needed to prepare for further education and careers in current or emerging professions, which may include high-skill, high-wage, or in-demand industry sectors or occupations, which shall be, at the secondary level, aligned with the challenging State academic standards adopted by a State under section 1111(b)(1) of the ESEA;

(2) Provides technical skill proficiency or a recognized postsecondary credential, which may include an industry-recognized credential, a certificate, or an associate degree; and

(3) May include prerequisite courses (other than a remedial course) [3] that meet the requirements of this paragraph (a);

(b) Include competency-based, work-based, or other applied learning that supports the development of academic knowledge, higher-order reasoning and problem-solving skills, work attitudes, employability skills, technical skills, and occupation-specific skills, and knowledge of all aspects of an industry, including entrepreneurship, of an individual;

(c) To the extent practicable, coordinate between secondary and postsecondary education programs through programs of study, which may include coordination through articulation agreements, early college high school programs, dual or concurrent enrollment program opportunities, or other credit transfer agreements that provide postsecondary credit or advanced standing; and

(d) May include career exploration at the high school level or as early as the middle grades (as such term is defined in section 8101 of the ESEA). (20 U.S.C. 2302(5)).

CTE concentrator means—

(a) At the secondary school level, a student served by an eligible recipient who has completed at least 2 courses in a single career and technical education program or program of study; and

(b) At the postsecondary level, a student enrolled in an eligible recipient who has—

(1) Earned at least 12 credits within a career and technical education program or program of study; or

(2) Completed such a program if the program encompasses fewer than 12 credits or the equivalent in total. (20 U.S.C. 2302(12))

Direct assistance to students means tuition, dependent care, transportation, books, and supplies that are necessary for a student to participate in a CTE program or program of study supported with NACTEP funds. (Notice of Final Requirements).

In-demand industry sector or occupation means—

(a) An industry sector that has a substantial current or potential impact (including through jobs that lead to economic self-sufficiency and opportunities for advancement) on the State, regional, or local economy, as appropriate, and that contributes to the growth or stability of other supporting businesses, or the growth of other industry sectors; or

(b) An occupation that currently has or is projected to have a number of positions (including positions that lead

[2] The correct name of this community is Metlakatla Indian Community. It is misspelled in the Alaska Native Claims Settlement Act, which is the source of this definition.

[3] Section 116(c)(2) of the Act provides that, notwithstanding the exclusion of remedial courses from the Act's definition of CTE, funds made available under NACTEP ''may be used to provide preparatory, refresher, and remedial education services that are designed to enable students to achieve success in career and technical education programs or programs of study.''

to economic self-sufficiency and opportunities for advancement) in an industry sector so as to have a significant impact on the State, regional, or local economy, as appropriate. (20 U.S.C. 2302(26); 29 U.S.C. 3102).

Indian means a person who is a member of an Indian Tribe. (20 U.S.C. 2302(27); 25 U.S.C. 5304(d)).

Indian Tribe means any Indian Tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. 1601 *et seq.*), which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians. (20 U.S.C. 2302(27); 25 U.S.C. 5304(e)).

Institution of higher education means—

(a) An educational institution in any State that—

(1) Admits as regular students only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such a certificate or persons who meet the requirements of section 1091(d) of this title;

(2) Is legally authorized within such State to provide a program of education beyond secondary education;

(3) Provides an educational program for which the institution awards a bachelor's degree or provides not less than a 2-year program that is acceptable for full credit toward such a degree, or awards a degree that is acceptable for admission to a graduate or professional degree program, subject to review and approval by the Secretary;

(4) Is a public or other nonprofit institution; and

(5) Is accredited by a nationally recognized accrediting agency or association or, if not so accredited, is an institution that has been granted pre-accreditation status by such an agency or association that has been recognized by the Secretary of Education for the granting of pre-accreditation status, and the Secretary has determined that there is satisfactory assurance that the institution will meet the accreditation standards of such an agency or association within a reasonable time.

(b) The term also includes—

(1) Any school that provides not less than a 1-year program of training to prepare students for gainful employment in a recognized occupation and that meets the provisions of paragraphs (1), (2), (4), and (5) of paragraph (a); and

(2) A public or nonprofit private educational institution in any State that, in lieu of the requirement in paragraph (a)(1) of this definition, admits as regular students individuals who are beyond the age of compulsory school attendance in the State in which the institution is located or, (B) who will be dually or concurrently enrolled in the institution and a secondary school. (20 U.S.C. 2302(30); 20 U.S.C. 1001(a) and (b)).

Professional development means activities that—

(a) are an integral part of eligible agency, eligible recipient, institution, or school strategies for providing educators (including teachers, principals, other school leaders, administrators, specialized instructional support personnel, career guidance and academic counselors, and paraprofessionals) with the knowledge and skills necessary to enable students to succeed in career and technical education, to meet challenging State academic standards under section 1111(b)(1) of ESEA, or to achieve academic skills at the postsecondary level; and

(b) Are sustained (not stand-alone, 1-day, or short-term workshops), intensive, collaborative, job-embedded, data-driven, and classroom-focused, to the extent practicable evidence-based, and may include activities that—

(1) Improve and increase educators'—

(A) Knowledge of the academic and technical subjects;

(B) Understanding of how students learn; and

(C) Ability to analyze student work and achievement from multiple sources, including how to adjust instructional strategies, assessments, and materials based on such analysis;

(2) Are an integral part of eligible recipients' improvement plans;

(3) Allow personalized plans for each educator to address the educator's specific needs identified in observation or other feedback;

(4) Support the recruitment, hiring, and training of effective educators, including educators who became certified through State and local alternative routes to certification;

(5) Advance educator understanding of—

(A) Effective instructional strategies that are evidence-based; and

(B) Strategies for improving student academic and technical achievement or substantially increasing the knowledge and teaching skills of educators;

(6) Are developed with extensive participation of educators, parents, students, and representatives of Indian Tribes (as applicable), of schools and institutions served under the Act;

(7) Are designed to give educators of students who are English learners in career and technical education programs or programs of study the knowledge and skills to provide instruction and appropriate language and academic support services to those students, including the appropriate use of curricula and assessments;

(8) As a whole, are regularly evaluated for their impact on increased educator effectiveness and improved student academic and technical achievement, with the findings of the evaluations used to improve the quality of professional development;

(9) Are designed to give educators of individuals with disabilities in career and technical education programs or programs of study the knowledge and skills to provide instruction and academic support services to those individuals, including positive behavioral interventions and supports, multi-tier system of supports, and use of accommodations;

(10) Include instruction in the use of data and assessments to inform and instruct classroom practice;

(11) Include instruction in ways that educators may work more effectively with parents and families;

(12) Provide follow-up training to educators who have participated in activities described in this definition that are designed to ensure that the knowledge and skills learned by the educators are implemented in the classroom;

(13) Promote the integration of academic knowledge and skills and relevant technical knowledge and skills, including programming jointly delivered to academic and career and technical education teachers; or

(14) Increase the ability of educators providing career and technical education instruction to stay current with industry standards. (20 U.S.C. 2302(40)).

Program of study means a coordinated, nonduplicative sequence of academic and technical content at the secondary and postsecondary level that—

(A) Incorporates challenging State academic standards, including those adopted by a State under section 1111(b)(1) of ESEA;

(B) Addresses both academic and technical knowledge and skills, including employability skills;

(C) Is aligned with the needs of industries in the economy of the State, region, Tribal community, or local area;

(D) Progresses in specificity (beginning with all aspects of an industry or career cluster and leading to more occupation-specific instruction);

(E) Has multiple entry and exit points that incorporate credentialing; and

(F) Culminates in the attainment of a recognized postsecondary credential. (20 U.S.C. 2302(41)).

Recognized postsecondary credential means a credential consisting of an industry-recognized certificate or certification, a certificate of completion of an apprenticeship, a license recognized by the State involved or Federal Government, or an associate or baccalaureate degree. (20 U.S.C. 2302(43); 29 U.S.C. 3102(52)).

Secondary school means a nonprofit institutional day or residential school, including a public secondary charter school, that provides secondary education, as determined under State law, except that the term does not include any education beyond grade 12. (20 U.S.C. 2302(44); 20 U.S.C. 7801(45)).

Special populations means—

(a) Individuals with disabilities;

(b) Individuals from economically disadvantaged families, including low-income youth and adults;

(c) Individuals preparing for non-traditional fields; (d) Single parents, including single pregnant women;

(e) Out-of-workforce individuals;

(f) English learners;

(g) Homeless individuals described in section 725 of the McKinney-Vento Homeless Assistance Act (42 U.S.C. 11434a);

(h) Youth who are in, or have aged out of, the foster care system; and

(i) Youth with a parent who—

(i) Is a member of the armed forces (as such term is defined in section 101(a)(4) of title 10, United States Code); and

(ii) Is on active duty (as such term is defined in section 101(d)(1) of such title). (20 U.S.C. 2302(48)).

Support services means services related to curriculum modification, equipment modification, classroom modification, supportive personnel (including paraprofessionals and specialized instructional support personnel), and instructional aids and devices. (20 U.S.C. 2302(50)).

Tribally controlled college or university means an institution of higher education that is formally controlled, or has been formally sanctioned, or chartered, by the governing body of an Indian Tribe or Tribes, except that no more than one such institution shall be recognized with respect to any such Tribe. (20 U.S.C. 2302(50); 25 U.S.C. 1801(a)(4)).

Tribal organization means the recognized governing body of any Indian Tribe; any legally established organization of Indians that is controlled, sanctioned, or chartered by such governing body or that is democratically elected by the adult members of the Indian community to be served by such organization and that includes the maximum participation of Indians in all phases of its activities: Provided, that, in any case where a contract is let or grant made to an organization to perform services benefiting more than one Indian Tribe, the approval of each such Indian Tribe shall be a prerequisite to the letting or making of such contract or grant. (20 U.S.C. 2302(53); 25 U.S.C. 5304(l)).

Work-based learning means sustained interactions with industry or community professionals in real workplace settings, to the extent practicable, or simulated environments at an educational institution that foster in-depth, firsthand engagement with the tasks required of a given career field, that are aligned to curriculum and instruction. (20 U.S.C. 2302 (55)).

Program Authority: 20 U.S.C. 2301, *et seq.,* particularly 2326(a)–(g).

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget (OMB) Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Guidance for Federal Financial Assistance in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) Notice of Final Requirements.

Note: As of October 1, 2024, grant applicants must follow the provisions stated in the OMB Guidance for Federal Financial Assistance (89 FR 30046, April 22, 2024) when preparing an application. For more information about these regulations please visit: *www.cfo.gov/resources-coffa/uniform-guidance/.*

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian Tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $21,000,000.

Note: Contingent upon the availability of funds and the quality of applications, the Department anticipates making awards for the first 12-month budget period using FY 2024 appropriations available in FY 2025 and FY 2025 appropriations, if any, that become available in FY 2026. The Department may make partial awards using FY 2024 appropriations available in FY 2025 and award the remaining funds using FY 2025 appropriations available in FY 2026 when they become available.

Contingent upon the availability of funds and the quality of applications, we may make additional awards later in FY 2026 or in subsequent years from the list of unfunded applications from this competition.

Estimated Range of Awards: $150,000 to $650,000 for each 12-month budget period (*i.e.,* a total of approximately $750,000 to $3,250,000 for a full 60 month project period).

Estimated Average Size of Awards: $500,000 for each 12-month budget period.

Estimated Number of Awards: 30–35.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* (a) The following entities are eligible to apply under this competition:

(1) A federally recognized Indian Tribe.

(2) A Tribal organization.

(3) An Alaska Native entity.

(4) A Bureau-funded school, except for a Bureau-funded school proposing to use its award to support general education secondary school programs.

(b) Any Tribe, Tribal organization, Alaska Native entity, or eligible Bureau-funded school may apply individually or as part of a consortium with one or more eligible Tribes, Tribal organizations, Alaska Native entities, or eligible Bureau-funded schools. (Eligible applicants seeking to apply for funds as a consortium must meet the requirements in 34 CFR 75.127 through 75.129, which apply to group applications.)

Note: A Tribal college or university may apply as a Tribal organization if it meets the criteria set forth in the definition of a Tribal organization, above.

Note: If you are a nonprofit organization, under 34 CFR 75.51, you may demonstrate your nonprofit status by providing: (1) proof that the Internal Revenue Service currently recognizes the applicant as an organization to which contributions are tax deductible under section 501(c)(3) of the Internal Revenue Code; (2) a statement from a State taxing body or the State attorney general certifying that the organization

is a nonprofit organization operating within the State and that no part of its net earnings may lawfully benefit any private shareholder or individual; (3) a certified copy of the applicant's certificate of incorporation or similar document if it clearly establishes the nonprofit status of the applicant; or (4) any item described above if that item applies to a State or national parent organization, together with a statement by the State or parent organization that the applicant is a local nonprofit affiliate.

2. a. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

b. *Supplement-Not-Supplant:* This competition involves supplement-not-supplant funding requirements. In accordance with section 211(a) of the Act (20 U.S.C. 2391(a)), funds under this program may not be used to supplant non-Federal funds used to carry out CTE activities. Further, the prohibition against supplanting also means that grantees will be required to use their negotiated restricted indirect cost rates under this program. (34 CFR 75.563)

We caution applicants not to plan to use funds under NACTEP to replace otherwise available non-Federal funding for direct assistance to students and family assistance programs. For example, NACTEP funds must not be used to supplant Tribal and other non-Federal funds with Federal funds in order to pay the costs of students' tuition, dependent care, transportation, books, supplies, and other costs associated with participation in a CTE program.

Funds under NACTEP should not be used to replace Federal student financial aid. The Act does not authorize the Secretary to fund projects that serve primarily as entities through which students may apply for and receive tuition and other financial assistance.

c. *Indirect Cost Rate Information:* This program uses a restricted indirect cost rate. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www.ed.gov/about/ed-offices/ofo#Indirect-Cost-Division*.

d. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Guidance for Federal Financial Assistance.

e. *Limitation on Services:* Section 215 of the Act (20 U.S.C. 2395) forbids the use of Perkins funds for the education of students prior to the middle grades. The term middle grades refers to grades 5 through 8, as defined in section 8101 of ESEA.

3. *Subgrantees:* Under 34 CFR 75.708 (b) and (c), a grantee under this competition may award subgrants—to directly carry out project activities described in its application—to the following types of entities: institutions of higher education, nonprofit organizations, Tribal organizations, Bureau-funded schools operating a secondary school CTE program, or Alaska Native entities. The grantee may only award subgrants to entities it has identified in an approved application, including any amendments to an approved application.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 7, 2022 (87 FR 75045) and available at *www.federalregister.gov/documents/2022/12/07/2022-26554/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs,* which contain requirements and information on how to submit an application.

Note: OCTAE invites an applicant to indicate whether it intends to consolidate its NACTEP grant funds into a current or future 477 plan in accordance with the provisions of Public Law 115–93, the Indian Employment, Training and Related Services Consolidation Act of 2017 (25 U.S.C. 3401 *et seq.*). Consistent with that statute, any request to consolidate NACTEP funds into a 477 plan must be made separately to the U.S. Department of Interior. For further information on the integration of grant funds under this program and related programs, contact the Division of Workforce Development, Office of Indian Services, Bureau of Indian Affairs, U.S. Department of the Interior at Office of Indian Services, Division of Workforce Development, Bureau of Indian Affairs, 1849 C Street NW, MS–3645–MIB, Washington, DC 20245, Telephone: (202) 219–3938.

NACTEP grantees who are in their last year of NACTEP funding from a previous grant and have currently integrated that previous grant under an approved 477 plan must apply for a new NACTEP grant under this competition by submitting an application that meets all of the requirements included in this notice. If such an applicant receives a new NACTEP grant under this competition and wants to consolidate the new NACTEP grant in a 477 plan, it must notify the U.S. Department of Interior that it plans to do so.

2. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for NACTEP, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Because we plan to make successful applications available to the public on the Department's website, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600 (Predisclosure Notification Procedures for Confidential Commercial Information), please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

4. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

5. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to 35 pages and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger, and no smaller than 10 pitch (characters per inch).

• Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the recommended page limit does apply to all of the application narrative.

6. *Notice of Intent to Apply:* The Department will be able to review grant applications more efficiently if we know the approximate number of applicants that intend to apply. Therefore, we strongly encourage each potential applicant to notify us of their intent to submit an application. To do so, please email the program contact person listed under **FOR FURTHER INFORMATION CONTACT** with the subject line ''Intent to Apply,'' and include the applicant's name and a contact person's name and email address. Applicants that do not submit a notice of intent to apply may still apply for funding; applicants that do submit a notice of intent to apply are not bound to apply or bound by the information provided.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this program are from section 116(e) of Perkins V (20 U.S.C. 2326(e)), the Notice of Final Requirements, or 34 CFR 75.210. The source is noted after each criterion.

The maximum score for each criterion is indicated in parentheses.

(a) *Need for project* (Up to 11 points). In determining the need for the proposed project, we consider the following factors:

(1) The extent to which the proposed project involves, coordinates with, or encourages Tribal economic development plans. (20 U.S.C. 2326(e)(1)). (Up to 5 points).

(2) The extent of the need for the services to be provided or the activities to be carried out by the proposed project, as evidenced by data on such phenomena as local labor market demand or occupational trends, or from surveys, recommendations from accrediting agencies, or Tribal economic development plans. (Notice of Final Requirements). (Up to 3 points)

(3) The extent to which the proposed project will provide support, resources, or services; or otherwise address the needs of the target population, including addressing the needs of underserved populations most affected by the issue, challenge, or opportunity, to be addressed by the proposed project and close gaps in educational opportunity. (34 CFR 75.210(a)(2)(iii)). (Up to 3 points)

(b) *Quality of the project design* (Up to 26 points). In determining the quality of the design of the proposed project, we consider the following factors:

(1) The extent to which the proposed project proposes specific, measurable targets, connected to strategies, activities, resources, outputs, and outcomes, and uses reliable administrative data to measure progress and inform continuous improvement. (34 CFR 75.210(c)(2)(v)). (Up to 16 points).

(2) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs, as evidenced by the applicant's description of programs and activities that align with the target population's needs. (Notice of Final Requirements). (Up to 10 points).

(c) *Quality of the project services* (Up to 24 points). In determining the quality of the services to be provided by the proposed project, we consider the following factors:

(1) The quality and sufficiency of strategies for ensuring equitable and adequate access and participation for project participants who experience barriers based on one or more of the following: economic disadvantage; gender; race; ethnicity; color; disability; age; language; living in a rural location; experiencing homelessness or housing insecurity; involvement with the justice system; and pregnancy, parenting, or caregiver status. This determination includes the steps developed and described in the form Equity For Students, Teachers, And Other Program Beneficiaries (OMB Control No. 1894–0005) (section 427 of the General Education Provisions Act (20 U.S.C. 1228a)). (34 CFR 75.210(d)(2)). (Up to 12 points).

(2) The extent to which the services to be provided by the proposed project will create opportunities for students to receive an industry-recognized credential; become employed in high-skill, high-wage, and high-demand occupations; or both. (Notice of Final Requirements). (Up to 7 points).

(3) The extent to which the training or professional development services to be provided by the proposed project would be of sufficient quality, intensity, and duration to lead to improvements in practice among the project staff and instructors, including the extent to which the proposed training and professional development plans address ways in which learning gaps will be addressed and how continuous review of performance will be conducted to identify training needs. (Notice of Final Requirements). (Up to 5 points).

(d) *Adequacy of resources* (Up to 19 points). In determining the adequacy of resources for the proposed project, we consider the following factors:

(1) The extent to which the budget is adequate to support the proposed project and the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project. (34 CFR 75.210(f)(2)(iii)). (Up to 7 points).

(2) The relevance and demonstrated commitment (*e.g.,* through written career and technical education agreements, memoranda of understanding, letters of support and commitment, or commitments to employ project participants, as appropriate) of the applicant, members of the consortium, local employers, or Tribal entities to be served by the project. (Notice of Final Requirements). (Up to 6 points).

(3) The extent to which the costs are reasonable in relation to the number of persons to be served, the depth and intensity of services, and the anticipated results and benefits. (34 CFR 75.210(f)(2)(iv)). (Up to 6 points).

(e) *Quality of the management plan* (Up to 20 points). In determining the quality of the management plan for the proposed project, we consider the following factors:

(1) The feasibility of the management plan to achieve project objectives and goals on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks. (34 CFR 75.210(g)(2)(i)). (Up to 10 points).

(2) The extent to which the time commitments of the project director and other key project personnel are appropriate and adequate to meet the objectives of the proposed project. (Notice of Final Requirements). (Up to 5 points).

(3) The extent to which the proposed project team maximizes diverse perspectives, for example by reflecting the lived experiences of project participants, or relevant experience working with the target population. (34 CFR 75.210(e)(3)(iv)). (Up to 5 points).

2. *Additional Selection Factor:* In accordance with the requirement in section 116(e) of the Act, we have included the following additional selection factor from the Notice of Final Requirements:

We will award five points to applications from Tribally controlled colleges or universities that—

(a) Are accredited or are candidates for accreditation by a nationally

recognized accreditation organization as an institution of postsecondary CTE; or

(b) Operate CTE programs that are accredited or are candidates for accreditation by a nationally recognized accreditation organization and issue certificates for completion of CTE programs (20 U.S.C. 2326(e)).

3. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

4. *Risk Assessment and Special Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this competition, the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose special conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

5. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management (SAM). You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Appeal process:* Any applicant denied funding under this NACTEP competition may request a hearing to review the Secretary's decision not to make the award. The Secretary will implement the appeal process in accordance with the procedures in 34 CFR 401.1. In accordance with those procedures, any applicant denied funding will have 30 calendar days to make a written request to the Secretary for a hearing to review the Secretary's decision. (25 U.S.C. 5321(b); 34 CFR 401.1).

2. *Indian Self-Determination Contracts:* Section 116(b)(2) of the Act provides that grants or contracts awarded under section 116 of the Act are subject to the terms and conditions of section 102 of the ISDEAA (25 U.S.C. 5321) and must be conducted in accordance with the provisions of sections 4, 5, and 6 of the Act of April 16, 1934 (25 U.S.C. 5345–5347) (Johnson-O'Malley Act), that are relevant to the programs administered under section 116(b) of the Act. The Act of April 16, 1934, authorizes the Secretary of the Interior to enter into contracts for the education of Indians and other purposes. Section 102 of the ISDEAA authorizes Indian Tribes to request self-determination contracts from the Department of Interior. Accordingly, an Indian Tribe or Tribal organization that has applied to the Secretary for funding under NACTEP and has been notified of its selection to be a funding recipient may submit a request to both the Secretary of Education (via the contact person listed under **FOR FURTHER INFORMATION CONTACT**) and the relevant Department of Interior contact person to operate its NACTEP project through a section 102 Indian self-determination contract.

After successful applicants are selected under this NACTEP competition, the Secretary will review any requests to operate a project under an Indian self-determination contract pursuant to the ISDEAA. If a request for an Indian self-determination contract is approved, the Indian Tribe or Tribal organization submitting the request will be required, to the extent possible, to operate its project in accordance with the ISDEAA, relevant provisions in sections 4, 5, and 6 of the Act of April 16, 1934 (25 U.S.C. 5345–5347), the Act, and the non-statutory program requirements specified in this notice.

The CTE programs provided through an Indian self-determination contract would have to be substantively the same as were proposed in the initial NACTEP application and approved by the Department. Any Indian Tribe or Tribal organization that is selected to receive funding under this competition, but whose request to operate the project under an Indian self-determination contract is denied, may appeal the denial to the Secretary. If you have questions about ISDEAA self-determination contracts, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

3. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may also notify you informally.

If your application is not evaluated or not selected for funding, we notify you.

4. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

5. *Open Licensing Requirement:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. The dissemination plan

can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

6. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. See the standards in 2 CFR 170.105 to determine whether you are covered by 2 CFR part 170.

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

7. *Performance Measures:* The Department has established the following performance measures for purposes of Department reporting under 34 CFR 75.110, which it will use to evaluate the overall performance of the grantee's project, as well as NACTEP as a whole:

(a) At the secondary level: An increase in—

(1) The percentage of CTE concentrators who graduate high school, as measured by—

(A) The four-year adjusted cohort graduation rate (defined in section 8101 of ESEA); and

(B) At the grantee's discretion, the extended-year adjusted cohort graduation rate (defined in section 8101 of ESEA);

(2) The percentage of CTE concentrators graduating from high school having attained postsecondary credits in the relevant CTE program earned through a dual or concurrent enrollment program or another credit transfer agreement;

(3) The percentage of CTE concentrators graduating from high school having participated in work-based learning;

(4) The percentage of CTE concentrators graduating from high school having attained a recognized postsecondary credential; and

(5) The percentage of CTE concentrators who, after exiting from secondary education, are in postsecondary education or advanced training, military service, or a service program, or are employed.

(b) At the postsecondary level: An increase in—

(1) The percentage of CTE concentrators who remain enrolled in postsecondary education, are in advanced training, military service, or a service program, or are employed; and

(2) The percentage of CTE concentrators who receive a recognized postsecondary credential.

Project-Specific Performance Measures:

In addition to the performance measures noted above, applicants may propose project-specific performance measures and performance targets consistent with the objectives of the proposed project. Examples of such project-specific performance measures could include student recruitment, student participation in work-based learning at the postsecondary level, and teacher and faculty participation in professional development.

Note: All grantees will be expected to submit a semi-annual and an annual performance report addressing these performance measures, to the extent that these performance measures apply to each grantee's NACTEP project.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, whether the grantee has made substantial progress in achieving the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package 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, braille, large print, audiotape, 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 Department documents published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site.

You may also access Department documents 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.

Luke Rhine,

Acting Assistant Secretary for Career, Technical, and Adult Education.

[FR Doc. 2025–00097 Filed 1–6–25; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2024–SCC–0115]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Evaluation of Teacher Residencies: District Perspective

AGENCY: Institute of Education Sciences (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a new information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before February 6, 2025.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link *www.reginfo.gov/public/do/PRAMain* to access the site. Find this information collection request (ICR) by

selecting ''Department of Education'' under ''Currently Under Review,'' then check the ''Only Show ICR for Public Comment'' checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the ''View Information Collection (IC) List'' link. Supporting statements and other supporting documentation may be found by clicking on the ''View Supporting Statement and Other Documents'' link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Meredith Bachman, (202) 245–7494.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Evaluation of Teacher Residencies: District Perspective.

OMB Control Number: 1850–NEW.

Type of Review: New ICR.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 31.

Total Estimated Number of Annual Burden Hours: 93.

Abstract: The U.S. Department of Education (ED)'s Institute of Education Sciences (IES) requests clearance for data collection activities to evaluate teacher residency programs' contributions to the teacher workforce. Specifically, this request covers the collection of data to understand the extent to which teacher residency programs funded by ED's Teacher Quality Partnership (TQP) grants help diversify the teacher pipeline and fill hard-to-staff teaching positions in their partner districts. The Higher Education Act established the TQP program to support partnerships between teacher preparation programs and high-need districts to implement teacher residency programs. The study will collect data on newly hired teachers from the school districts and charter school networks (referred to throughout as ''districts'') that partner with TQP grantees. If some districts are unable to provide data on new hires from TQP-funded residency programs, we will collect those data from TQP grantees.

Dated: January 2, 2025.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2025–00010 Filed 1–6–25; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2246–065]

Yuba County Water Agency; Notice of Reasonable Period of Time for Water Quality Certification Application

On December 30, 2024, the Yuba County Water Agency submitted to the Federal Energy Regulatory Commission (Commission) a copy of its application for Clean Water Act section 401(a)(1) water quality certification filed with the California State Water Resources Control Board (Water Board), in conjunction with the above captioned project. The submittal also included a response from the Water Board stating that it received the application on the same day. Pursuant to section 5.23(b) of the Commission's regulations,[1] we hereby notify the Water Board of the following:

Date of Receipt of the Certification Request: December 30, 2024.

Reasonable Period of Time to Act on the Certification Request: December 30, 2025.

If the Water Board fails or refuses to act on the water quality certification request on or before the above date, then the certifying authority is deemed waived pursuant to section 401(a)(1) of the Clean Water Act, 33 U.S.C. 1341(a)(1).

Dated: December 31, 2024.

Debbie-Anne Reese,

Secretary.

[FR Doc. 2025–00087 Filed 1–6–25; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 5.23(b).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2391–053]

PE Hydro Generation, LLC; Notice of Intent To Prepare an Environmental Assessment

On January 3, 2022, PE Hydro Generation, LLC filed a subsequent minor license application for the 750-kilowatt Warren Hydroelectric Project No. 2391 (project). The project is located on the Shenandoah River, near the Town of Front Royal, in Warren County, Virginia.

In accordance with the Commission's regulations, on October 18, 2024, Commission staff issued a notice that the project was ready for environmental analysis (REA Notice). Based on the information in the record, staff does not anticipate that licensing the project would constitute a major Federal action significantly affecting the quality of the human environment. Therefore, staff intends to prepare an Environmental Assessment (EA) on the application to license the project.[1]

The EA will be issued and circulated for review by all interested parties. All comments filed on the EA will be analyzed by staff and considered in the Commission's final licensing decision.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members, and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

The application will be processed according to the following schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Commission issues EA	December 31, 2025.

Any questions regarding this notice may be directed to Kristine Sillett at (202) 502–6575 or *kristine.sillett@ferc.gov.*

[1] In accordance with the Council on Environmental Quality's regulations, the unique identification number for documents relating to this environmental review is EAXX–019–20–000–1734604160. 40 CFR 1501.5(c)(4) (2024).

Dated: December 31, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2025–00089 Filed 1–6–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2610–012]

Northern States Power Company; Notice of Reasonable Period of Time for Water Quality Certification Application

On December 16, 2024, the Michigan Department of Environment, Great Lakes, and Energy (Michigan EGLE) submitted to the Federal Energy Regulatory Commission (Commission) notice that it received a request for a Clean Water Act section 401(a)(1) water quality certification as defined in 40 CFR 121.5, from Northern States Power Company, in conjunction with the above captioned project on December 6, 2024. Pursuant to section 4.34(b)(5) of the Commission's regulations,[1] we hereby notify Michigan EGLE of the following dates.

Date of Receipt of the Certification Request: December 6, 2024.

Reasonable Period of Time to Act on the Certification Request: One year, December 6, 2025.

If Michigan EGLE fails or refuses to act on the water quality certification request on or before the above date, then the certifying authority is deemed waived pursuant to section 401(a)(1) of the Clean Water Act, 33 U.S.C. 1341(a)(1).

Dated: December 31, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2025–00084 Filed 1–6–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2587–066]

Northern States Power Company; Notice of Reasonable Period of Time for Water Quality Certification Application

On December 16, 2024, the Michigan Department of Environment, Great Lakes, and Energy (Michigan EGLE) submitted to the Federal Energy Regulatory Commission (Commission) notice that it received a request for a Clean Water Act section 401(a)(1) water quality certification as defined in 40 CFR 121.5, from Northern States Power Company, in conjunction with the above captioned project on December 6, 2024. Pursuant to section 4.34(b)(5) of the Commission's regulations,[1] we hereby notify Michigan EGLE of the following dates.

Date of Receipt of the Certification Request: December 6, 2024.

Reasonable Period of Time to Act on the Certification Request: One year, December 6, 2025.

If Michigan EGLE fails or refuses to act on the water quality certification request on or before the above date, then the certifying authority is deemed waived pursuant to section 401(a)(1) of the Clean Water Act, 33 U.S.C. 1341(a)(1).

Dated: December 31, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2025–00085 Filed 1–6–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC25–35–000.

Applicants: West Deptford Energy, LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act of West Deptford Energy, LLC.

Filed Date: 12/27/24.

Accession Number: 20241227–5234.

Comment Date: 5 p.m. ET 1/17/25.

Docket Numbers: EC25–36–000.

Applicants: Brookfield Smoky Mountain Hydropower LP, Smoky Mountain Transmission LLC.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of Brookfield Smoky Mountain, et al.

Filed Date: 12/30/24.

Accession Number: 20241230–5391.

Comment Date: 5 p.m. ET 1/21/25.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2881–043; ER15–647–009; ER15–2191–008; ER16–750–009; ER16–2659–007; ER19–2005–003; ER20–136–004; ER21–2287–003.

Applicants: Glass Sands Wind Energy, LLC, Reading Wind Energy, LLC, Wildhorse Wind Energy, LLC, Grant Plains Wind, LLC, Bethel Wind Farm LLC, Grant Wind, LLC, Kay Wind, LLC, Alabama Power Company.

Description: Triennial Market Power Analysis for Southwest Power Pool Inc. Region of Alabama Power Co., et al.

Filed Date: 12/30/24.

Accession Number: 20241230–5393.

Comment Date: 5 p.m. ET 2/28/25

Docket Numbers: ER10–2906–021; ER19–1716–009; ER24–2581–001; ER24–2611–001.

Applicants: Energy Prepay IV, LLC, Energy Prepay III, LLC, Morgan Stanley Energy Structuring, L.L.C., Morgan Stanley Capital Group Inc.

Description: Triennial Market Power Analysis for Southwest Region of Morgan Stanley Capital Group Inc., et al. under ER10–2906, et al.

Filed Date: 12/30/24.

Accession Number: 20241230–5401.

Comment Date: 5 p.m. ET 2/28/25.

Docket Numbers: ER10–3050–015; ER10–3053–015.

Applicants: Whitewater Hill Wind Partners, LLC, Cabazon Wind Partners, LLC.

Description: Triennial Market Power Analysis for Southwest Region of Cabazon Wind Partners, LLC, et al.

Filed Date: 12/30/24.

Accession Number: 20241230–5399.

Comment Date: 5 p.m. ET 2/28/25.

Docket Numbers: ER10–3117–012.

Applicants: Lea Power Partners, LLC.

Description: Triennial Market Power Analysis for Southwest Power Pool Inc. Region of Lea Power Partners, LLC.

Filed Date: 12/31/24.

Accession Number: 20241231–5186.

Comment Date: 5 p.m. ET 3/3/25.

Docket Numbers: ER11–3576–018; ER11–3401–017.

Applicants: Golden Spread Panhandle Wind Ranch, LLC, Golden Spread Electric Cooperative, Inc.

Description: Triennial Market Power Analysis for Southwest Power Pool Inc. Region of Golden Spread Electric Cooperative, Inc., et al.

Filed Date: 12/31/24.

Accession Number: 20241231–5204.

Comment Date: 5 p.m. ET 3/3/25.

Docket Numbers: ER14–2499–008.

Applicants: Oneta Power, LLC.

Description: Triennial Market Power Analysis for Southwest Power Pool Inc. Region of Oneta Power, LLC.

Filed Date: 12/31/24.

Accession Number: 20241231–5184.

Comment Date: 5 p.m. ET 3/3/25.

Docket Numbers: ER19–1575–014; ER10–2488–031; ER13–1586–026;

[1] 18 CFR 4.34(b)(5).

[1] 18 CFR 4.34(b)(5).

ER14–2871–025; ER15–463–024; ER15–621–024; ER15–622–024; ER16–72–020; ER16–182–020; ER16–902–017; ER17–47–017; ER17–48–018; ER18–47–017; ER18–2240–013; ER18–2241–013; ER19–1660–013; ER19–1662–013; ER20–71–013; ER20–72–013; ER20–75–013; ER20–76–015; ER20–77–013; ER20–79–013; ER21–1368–009; ER21–2782–010; ER22–149–011; ER22–2419–007; ER22–2420–007; ER23–562–007; ER23–1048–007; ER23–2001–007; ER24–916–003; ER24–917–004; ER24–2257–003; ER24–2258–003.

Applicants: Lockhart CL ESS II, LLC, Lockhart CL ESS I, LLC, Placerita ESS, LLC, Beaumont ESS, LLC, Sagebrush ESS II, LLC, Lockhart ESS, LLC, TGP Energy Management II, LLC, Lockhart Solar PV II, LLC, Lockhart Solar PV, LLC, Sagebrush Line, LLC, Sagebrush ESS, LLC, Valley Center ESS, LLC, Voyager Wind IV Expansion, LLC, Painted Hills Wind Holdings, LLC, Oasis Plains Wind, LLC, Oasis Alta, LLC, Coachella Wind Holdings, LLC, Coachella Hills Wind, LLC, Mojave 16/17/18 LLC, Mojave 3/4/5 LLC, Garnet Wind, LLC, Yavi Energy, LLC, Voyager Wind II, LLC, Terra-Gen Mojave Windfarms, LLC, DifWind Farms LTD VI, Voyager Wind I, LLC, Cameron Ridge II, LLC, San Gorgonio Westwinds II—Windustries, LLC, Ridgetop Energy, LLC, Pacific Crest Power, LLC, San Gorgonio Westwinds II, LLC, Cameron Ridge, LLC, TGP Energy Management, LLC, Oasis Power Partners, LLC, Alta Oak Realty, LLC.

Description: Triennial Market Power Analysis for Southwest Region of Alta Oak Realty, LLC et al.

Filed Date: 12/30/24.

Accession Number: 20241230–5395.

Comment Date: 5 p.m. ET 2/28/25.

Docket Numbers: ER19–2534–004; ER19–2434–004.

Applicants: Citizens Imperial Solar LLC, Citizens Energy Corporation.

Description: Triennial Market Power Analysis for Southwest Region of Citizens Energy Corporation, et al.

Filed Date: 12/30/24.

Accession Number: 20241230–5400.

Comment Date: 5 p.m. ET 2/28/25.

Docket Numbers: ER20–539–007; ER16–581–015; ER16–2271–014; ER17–1370–014; ER19–828–007; ER20–1338–006; ER20–2505–005; ER21–1254–008; ER21–2204–008; ER21–2279–004; ER23–2712–002.

Applicants: North Bend Wind Project, LLC, Iron Star Wind Project, LLC, ENGIE Power & Gas LLC, Genbright LLC, Triple H Wind Project, LLC, King Plains Wind Project, LLC, Solomon Forks Wind Project, LLC, ENGIE Energy Marketing NA, Inc., ENGIE Resources LLC, ENGIE Portfolio Management, LLC, East Fork Wind Project, LLC.

Description: Triennial Market Power Analysis for Southwest Power Pool Inc. Region of East Fork Wind Project, LLC, et al.

Filed Date: 12/30/24.

Accession Number: 20241230–5394.

Comment Date: 5 p.m. ET 2/28/25.

Docket Numbers: ER21–2270–001; ER18–784–007; ER20–956–006.

Applicants: Thunderhead Wind Energy LLC, Upstream Wind Energy LLC, Jayhawk Wind, LLC.

Description: Triennial Market Power Analysis for Southwest Power Pool Inc. Region of Jayhawk Wind, LLC, et al.

Filed Date: 12/30/24.

Accession Number: 20241230–5397.

Comment Date: 5 p.m. ET 2/28/25.

Docket Numbers: ER21–2652–006; ER20–1970–002.

Applicants: Diamond Spring, LLC, Caddo Wind, LLC.

Description: Triennial Market Power Analysis for Southwest Power Pool Inc. Region of Caddo Wind, LLC, et al.

Filed Date: 12/30/24.

Accession Number: 20241230–5396.

Comment Date: 5 p.m. ET 2/28/25.

Docket Numbers: ER22–1439–011; ER21–1369–010; ER21–1371–010; ER21–1373–011; ER21–1376–011; ER22–1440–011; ER22–1441–011; ER22–1442–009.

Applicants: EdSan 1B Group 3, LLC, EdSan 1B Group 2, LLC, EdSan 1B Group 1 Sanborn, LLC, Sanborn Solar 1A, LLC, Edwards Solar 1A, LLC, Edwards Sanborn Storage II, LLC, Edwards Sanborn Storage I, LLC, EdSan 1B Group 1 Edwards, LLC.

Description: Triennial Market Power Analysis for Southwest Region of EdSan 1B Group 1 Edwards, LLC, et al.

Filed Date: 12/30/24.

Accession Number: 20241230–5398.

Comment Date: 5 p.m. ET 2/28/25.

Docket Numbers: ER23–1277–004.

Applicants: Aron Energy Prepay 23 LLC.

Description: Triennial Market Power Analysis for Southwest Region of Aron Energy Prepay 23 LLC.

Filed Date: 12/31/24.

Accession Number: 20241231–5199.

Comment Date: 5 p.m. ET 3/3/25.

Docket Numbers: ER24–227–005.

Applicants: RPC Power, LLC.

Description: Triennial Market Power Analysis for Southwest Power Pool Inc. Region of RPC Power, LLC.

Filed Date: 12/31/24.

Accession Number: 20241231–5191.

Comment Date: 5 p.m. ET 3/3/25.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *https://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov*.

Dated: December 31, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2025–00093 Filed 1–6–25; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER17–1329–005.

Applicants: J.P. Morgan Ventures Energy Corporation.

Description: Compliance filing: MBR Compliance Filing of JPMVEC to be effective 1/20/2025.

Filed Date: 12/31/24.

Accession Number: 20241231–5237.

Comment Date: 5 p.m. ET 1/21/25.

Docket Numbers: ER25–830–000.

Applicants: Fitchburg Gas and Electric Light Company.

Description: 205(d) Rate Filing: Wholesale Distribution Tariff Baseline to be effective 3/1/2026.

Filed Date: 12/30/24.
Accession Number: 20241230–5384.
Comment Date: 5 p.m. ET 1/21/25.

Docket Numbers: ER25–831–000.
Applicants: Westlands Transmission Project Owner, LLC.
Description: 205(d) Rate Filing: Amendments to TSAs and Request for Waiver to be effective 12/31/9998.
Filed Date: 12/31/24.
Accession Number: 20241231–5001.
Comment Date: 5 p.m. ET 1/21/25.

Docket Numbers: ER25–832–000.
Applicants: Consolidated Edison Company of New York, Inc.
Description: 205(d) Rate Filing: PASNY RY3 and NYPA REACH to be effective 1/1/2025.
Filed Date: 12/31/24.
Accession Number: 20241231–5003.
Comment Date: 5 p.m. ET 1/21/25.

Docket Numbers: ER25–833–000.
Applicants: American Transmission Systems, Incorporated.
Description: 205(d) Rate Filing: ATSI submits one Wholesale Load or Affiliate Counter Party CSA, SA No. 6641 to be effective 3/2/2025.
Filed Date: 12/31/24.
Accession Number: 20241231–5043.
Comment Date: 5 p.m. ET 1/21/25.

Docket Numbers: ER25–834–000.
Applicants: MidAmerican Central California Transco, LLC.
Description: 205(d) Rate Filing: 2024 Annual Update TRBAA FIling to be effective 12/1/2024.
Filed Date: 12/31/24.
Accession Number: 20241231–5100.
Comment Date: 5 p.m. ET 1/21/25.

Docket Numbers: ER25–835–000.
Applicants: Golden Spread Electric Cooperative, Inc.
Description: 205(d) Rate Filing: WPC Amendments Ex B Formula Rate Template to be effective 1/1/2025.
Filed Date: 12/31/24.
Accession Number: 20241231–5229.
Comment Date: 5 p.m. ET 1/21/25.

Docket Numbers: ER25–836–000.
Applicants: J.P. Morgan Ventures Energy Corporation.
Description: Tariff Amendment: Reactive Tariff Cancellation of JPMVEC to be effective 3/3/2025.
Filed Date: 12/31/24.
Accession Number: 20241231–5240.
Comment Date: 5 p.m. ET 1/21/25.

Docket Numbers: ER25–837–000.
Applicants: J.P. Morgan Ventures Energy Corporation.
Description: Tariff Amendment: Rate Schedule No. 1 Cancellation of JPMVEC to be effective 3/3/2025.
Filed Date: 12/31/24.
Accession Number: 20241231–5243.
Comment Date: 5 p.m. ET 1/21/25.

Docket Numbers: ER25–838–000.
Applicants: Wabash Valley Power Association, Inc.
Description: Tariff Amendment: Notice of Cancellation of Volume 2 of Formulary Rate Tariff to be effective 1/1/2025.
Filed Date: 12/31/24.
Accession Number: 20241231–5292.
Comment Date: 5 p.m. ET 1/21/25.

Docket Numbers: ER25–839–000.
Applicants: Entergy Louisiana, LLC.
Description: 205(d) Rate Filing: ELL–1803 Elec Coop Inc. WDS Agreement to be effective 1/1/2025.
Filed Date: 12/31/24.
Accession Number: 20241231–5344.
Comment Date: 5 p.m. ET 1/21/25.

Docket Numbers: ER25–840–000.
Applicants: Consolidated Edison Company of New York, Inc.
Description: 205(d) Rate Filing: WDS RY3 12–2024 to be effective 1/1/2025.
Filed Date: 12/31/24.
Accession Number: 20241231–5352.
Comment Date: 5 p.m. ET 1/21/25.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

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Dated: December 31, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2025–00092 Filed 1–6–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. Each filing may be viewed

on the Commission's website at *https://www.ferc.gov* using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Docket Nos.	File date	Presenter or requester
Prohibited:		
NONE.		
Exempt:		
1. P–14787–004	12–20–2024	FERC Staff.[1]

[1] Memorandum of email communication dated 12/20/24 with the Bureau of Land Management and rPlus.

Dated: December 31, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2025–00082 Filed 1–6–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC25–3–000]

Commission Information Collection Activities (FERC–725); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC 725, Certification of Electric Reliability Organization; Procedures for Electric Reliability Standards. There were no changes made to the reporting requirements for this information collection.

DATES: Comments on the collection of information are due March 10, 2025.

ADDRESSES: You may submit copies of your comments (identified by Docket No. IC25–3–000) by one of the following methods:

Electronic filing through *https://www.ferc.gov,* is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, not in scanned or picture format.
- For those unable to file electronically, comments may be filed by USPS mail or by other delivery methods:

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

○ *All other delivery services:* Federal Energy Regulatory Commission, Office of the Secretary, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *https://www.ferc.gov*. For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *https://www.ferc.gov*.

FOR FURTHER INFORMATION CONTACT: Kayla Williams may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–6468.

SUPPLEMENTARY INFORMATION:

Title: FERC–725, Certification of Electric Reliability Organization; Procedures for Electric Reliability Standards.

OMB Control No.: 1902–0225.

Type of Request: Three-year extension of the FERC–725 information collection requirements with no changes to the current reporting and recordkeeping requirements.

Abstract: The FERC–725 contains the following information collection elements:

Self-Assessment and ERO (Electric Reliability Organization) Application: The Commission requires the ERO to submit to FERC a performance assessment report every five years. The next assessment is due in 2025. Each Regional Entity submits a performance assessment report to the ERO.

Submitting an application to become the ERO is also part of this collection.[1]

Reliability Assessments: 18 CFR 39.11 requires the ERO to assess the reliability and adequacy of the Bulk-Power System in North America. Subsequently, the ERO must report to the Commission on its findings. Regional entities perform similar assessments within individual regions. Currently the ERO submits to FERC three assessments each year: long term, winter, and summer. In addition, the North American Electric Reliability Corporation (NERC, the Commission-approved ERO) also submits various other assessments as needed.

Reliability Standards Development: Under section 215 of the Federal Power Act (FPA),[2] the ERO is charged with developing Reliability Standards. Regional Entities may also develop regional specific standards and have standard experts on staff to work with entities below the regional level.

Reliability Compliance: Reliability Standards are mandatory and enforceable upon approval by the Commission. In addition to the specific information collection requirements contained in each standard (cleared under other information collections), there are general compliance, monitoring and enforcement information collection requirements imposed on applicable entities. Audits, spot checks, self-certifications, exception data submittals, violation reporting, and mitigation plan confirmation are included in this area.

Stakeholder Survey: The ERO uses a stakeholder survey to solicit feedback from registered entities [3] in preparation for its five-year self-performance assessment. The Commission assumes that the ERO will perform another survey prior to the 2025 self-assessment.

Other Reporting: This category refers to all other reporting requirements imposed on the ERO or regional entities in order to comply with the Commission's regulations. For example, FERC may require NERC to submit a special reliability assessment or inquiry. This category captures these types of

[1] The Commission does not expect any new ERO applications to be submitted in the next five years and is not including any burden for this requirement in the burden estimate. FERC still seeks to renew the regulations pertaining to a new ERO application under this renewal but is expecting the burden to be zero for the foreseeable future. 18 CFR 39.3 contains the regulation pertaining to ERO applications.

[2] 16 U.S.C. 824o.

[3] A ''registered entity'' is an entity that is registered with the ERO. All Bulk-Power System owners, operators and users are required to register with the ERO. Registration is the basis for determining the Reliability Standards with which an entity must comply. See *http://www.nerc.com/page.php?cid=3%7C25* for more details.

one-time filings required of NERC or the Regions.

The Commission implements its responsibilities through 18 CFR part 39.

Type of Respondent: Electric Reliability Organization, Regional entities, and registered entities.

Estimate of Annual Burden:[4] The Commission estimates the total annual burden and cost[5] for this information collection in the table below. For hourly cost (for wages and benefits), we estimate that 70% of the time is spent by Electrical Engineers (code 17–2071, at $79.31/hr.), 10% of the time is spent by Legal (code 23–0000, at $162.66/hr.), and 20% by Information and Record Clerk (code 43–4199, at $44.74/hr.). Therefore, we use the weighted hourly cost (for wages and benefits) of $80.73(rounded) {or [(0.70) * ($79.13/hr.)] + [(0.10) * $162.66/hr.] + [(0.20) * $44.74/hr.]}.

FERC–725, CERTIFICATION OF ELECTRIC RELIABILITY ORGANIZATION; PROCEDURES FOR ELECTRIC RELIABILITY STANDARDS

Type of respondent	Type of reporting requirement	Number of respondents[6] (A)	Annual number of responses per respondent[7] (B)	Total number of responses (A) × (B) = (C)	Average burden hours & cost ($) per response (rounded) (D)	Estimated total annual burden hours & cost ($) (rounded) (C) × (D)
Electric Reliability Organization (ERO).	Self-Assessment.	1	.2	.2	4,160 hrs.; $335,837.	832 hrs.; $67,167.
	Reliability Assessments.		4	4	10,400 hrs.; $839,592.	41,600 hrs.; $3,358,368.
	Reliability Compliance.		2	2	18,720 hrs.; $1,511,266.	37,440 hrs.; $3,022,531.
	Standards Development.		1	1	24,960 hrs.; $2,015,021.	24,960 hrs.; $2,015,021.
	Other Reporting.		1	1	4,160 hrs.; $335,836.	4,160 hrs.; $335,836.
ERO, Sub-Total	.....	.....	.....	.....	.....	*108,992 hrs.; $8,798,924.*
Regional Entities	Self-Assessment.	6	.2	1.2	4,160 hrs.; $335,836.	4,992 hrs.; $403,004.
	Reliability Assessments.		1	6	12,480 hrs.; $1,007,510.	74,880 hrs.; $6,045,062.
	Reliability Compliance.		1	6	47,840 hrs.; $3,862,123.	287,040 hrs.; $23,172,739.
	Standards Development.		1	6	1,560 hrs.; $125,938.	9,360 hrs.; $755,632.
	Other Reporting.		1	6	1,040 hrs.; $83,959	6,240 hrs.; $503,755.
Regional Entities, Sub-Total.	.....	.....	.....	.....	.....	*382,512 hrs.; $30,880,194.*
Registered Entities	Stakeholder Survey.	3,735	.2	747	8 hrs.; $646	5,976 hrs.; $482,442.
	Reliability Compliance.		1	3,735	180 hrs.; $14,531	672,300 hrs.; $54,274,779.
Registered Entities, Sub-Total.	.....	.....	.....	.....	.....	*678,276 hrs.; $54,757,221.*
Total Burden Hrs. and Cost.	.....	.....	.....	.....	.....	1,169,870 hrs.; $94,436,339.

Comments: Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: December 31, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2025–00083 Filed 1–6–25; 8:45 am]

BILLING CODE 6717–01–P

[4] ''Burden'' is the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 CFR 1320.3.

[5] Costs (for wages and benefits) are based on wage figures from the Bureau of Labor Statistics (BLS) for May 2024 (at *https://www.bls.gov/oes/current/naics2_22.htm*) and benefits information (at *https://www.bls.gov/news.release/ecec.nr0.htm*).

[6] Estimated number of respondents is taken from the November 20, 2024, NERC Compliance Registration tables. NERC is the only ERO and there are six regional entities (MRO, WECC, RF, SERC, NPCC and Texas RE). The estimated 3,735 represents the number of only US unique entities.

[7] In instances where the number of responses per respondent is ''1,'' the Commission Staff thinks that the actual number of responses varies and cannot be estimated accurately.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: PR25–24–000.
Applicants: NET Mexico Pipeline Partners, LLC.
Description: 284.123(g) Rate Filing: Petition for Approval of Rates for Transportation Service.
Filed Date: 12/30/24.
Accession Number: 20241230–5353.
Comment Date: 5 p.m. ET 1/17/25.
284.123(g) Protest: 5 p.m. ET 2/28/25.

Docket Numbers: RP25–315–000.
Applicants: Alliance Pipeline L.P.
Description: 4(d) Rate Filing: Negotiated Rates—Releases—2025–01–01 to be effective 1/1/2025.
Filed Date: 12/30/24.
Accession Number: 20241230–5299.
Comment Date: 5 p.m. ET 1/13/25.

Docket Numbers: RP25–316–000.
Applicants: Florida Gas Transmission Company, LLC.
Description: Compliance filing: Annual Accounting Report on 12–31–24 to be effective N/A.
Filed Date: 12/31/24.
Accession Number: 20241231–5004.
Comment Date: 5 p.m. ET 1/13/25.

Docket Numbers: RP25–317–000.
Applicants: Florida Gas Transmission Company, LLC.
Description: 4(d) Rate Filing: Out of Cycle Fuel Filing on 12–31–24 to be effective 2/1/2025.
Filed Date: 12/31/24.
Accession Number: 20241231–5005.
Comment Date: 5 p.m. ET 1/13/25.

Docket Numbers: RP25–318–000.
Applicants: Sea Robin Pipeline Company, LLC.
Description: 4(d) Rate Filing: Annual Flowthrough Crediting Mechanism Filing 12–31–24 to be effective 2/1/2025.
Filed Date: 12/31/24.
Accession Number: 20241231–5006.
Comment Date: 5 p.m. ET 1/13/25.

Docket Numbers: RP25–319–000.
Applicants: Mountain Valley Pipeline, LLC.
Description: 4(d) Rate Filing: Negotiated Rate Agreements—1/1/2025 to be effective 1/1/2025.
Filed Date: 12/31/24.
Accession Number: 20241231–5013.
Comment Date: 5 p.m. ET 1/13/25.

Docket Numbers: RP25–320–000.
Applicants: Rover Pipeline LLC.
Description: 4(d) Rate Filing: Amended Non-Conforming Agreement—Antero to be effective 1/1/2025.
Filed Date: 12/31/24.
Accession Number: 20241231–5103.
Comment Date: 5 p.m. ET 1/13/25.

Docket Numbers: RP25–321–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: 4(d) Rate Filing: Negotiated Rate Agreement Update (Hartree Jan 25) to be effective 1/1/2025.
Filed Date: 12/31/24.
Accession Number: 20241231–5162.
Comment Date: 5 p.m. ET 1/13/25.

Docket Numbers: RP25–322–000.
Applicants: Columbia Gulf Transmission, LLC.
Description: 4(d) Rate Filing: Revisions to GT&C VII.19 to be effective 2/1/2025.
Filed Date: 12/31/24.
Accession Number: 20241231–5197.
Comment Date: 5 p.m. ET 1/13/25.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP22–1072–005.
Applicants: Tuscarora Gas Transmission Company.
Description: Compliance filing: Tuscarora Rate Case Motion to Place Period 2 Settlement Rates Into Effect to be effective 2/1/2025.
Filed Date: 12/31/24.
Accession Number: 20241231–5155.
Comment Date: 5 p.m. ET 1/13/25.

Docket Numbers: RP23–1099–000.
Applicants: Gas Transmission Northwest LLC.
Description: Refund Report: Settlement Refund Report to be effective N/A.
Filed Date: 12/30/24.
Accession Number: 20241230–5294.
Comment Date: 5 p.m. ET 1/13/25.

Docket Numbers: RP24–781–008.
Applicants: Algonquin Gas Transmission, LLC.
Description: Compliance filing: Algonquin Gas Transmission, LLC X–33 Revised Tariff Record Filing RP24–781 to be effective 1/1/2025.
Filed Date: 12/30/24.
Accession Number: 20241230–5366.
Comment Date: 5 p.m. ET 1/13/25.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov*.

Dated: December 31, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2025–00091 Filed 1–6–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP25–30–000]

Florida Gas Transmission, LLC; Notice of Application and Establishing Intervention Deadline

Take notice that on December 13, 2024, Florida Gas Transmission Company, LLC (FGT), 1300 Main Street, Houston, Texas 77002, filed an application under section 7(c) of the Natural Gas Act (NGA), and part 157 of the Commission's regulations requesting authorization for its South Central Louisiana Project (Project). The Project involves the uprate of one existing natural gas-fired compressor turbine from 6,500 to 7,700 horsepower (HP) at FGT's Compressor Station (CS) 7.5 in St. Landry Parish, Louisiana; and an installation of one new 15,900 HP natural gas-fired compressor unit at FGT's CS 8 in East Baton Rouge Parish,

Louisiana. The Project will provide additional firm transportation capacity of up to 75,000 million British thermal units per day of natural gas to Tampa Electric Company. FGT estimates the total cost of the Project to be $43,357,590 and proposes a negotiated rate with service provided under Rate Schedule FTS–WD–3 for the cost recovery, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

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*). 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.

User assistance is available for eLibrary and the Commission's website during normal business hours from FERC 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*.

Any questions regarding the proposed project should be directed to Blair Lichtenwalter, Senior Director of Certificates, Florida Gas Transmission Company, LLC, 1300 Main Street, Houston, Texas, 77002, by phone at (713) 989–2605, or by email at *blairlichtenwalter@energytransfer.com*.

Pursuant to section 157.9 of the Commission's Rules of Practice and Procedure,[1] within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

[1] 18 CFR 157.9.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file comments on the project, you can protest the filing, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time on January 30, 2025. How to file protests, motions to intervene, and comments is explained below.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov*.

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections, to the project as a whole or specific aspects of the project. The more specific your comments, the more useful they will be.

Protests

Pursuant to sections 157.10(a)(4)[2] and 385.211[3] of the Commission's regulations under the NGA, any person[4] may file a protest to the application. Protests must comply with the requirements specified in section 385.2001[5] of the Commission's regulations. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

To ensure that your comments or protests are timely and properly recorded, please submit your comments on or before January 30, 2025.

[2] 18 CFR 157.10(a)(4).

[3] 18 CFR 385.211.

[4] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[5] 18 CFR 385.2001.

There are three methods you can use to submit your comments or protests to the Commission. In all instances, please reference the Project docket number CP25–30–000 in your submission.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments or protests electronically by using the eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments or protests by mailing them to the following address below. Your written comments must reference the Project docket number (CP25–30–000).

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov*.

Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list, and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. However, the filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses,

municipalities, and other entities,[6] has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [7] and the regulations under the NGA [8] by the intervention deadline for the project, which is January 30, 2025. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp*.

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket number CP25–30–000 in your submission.

(1) You may file your motion to intervene by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Intervention.'' The eFiling feature includes a document-less intervention option; for more information, visit *https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf*.; or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below. Your motion to intervene must reference the Project docket number CP25–30–000.

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of motions to intervene (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov*.

Protests and motions to intervene must be served on the applicant either by mail at: Blair Lichtenwalter, Senior Director of Certificates, 1300 Main Street, Houston, Texas 77002, or by email (with a link to the document) at *blairlichtenwalter@energytransfer.com*. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed [9] motions to intervene are automatically granted by operation of Rule 214(c)(1).[10] Motions to intervene that are filed after the intervention deadline are untimely, and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.[11] A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Intervention Deadline: 5:00 p.m. Eastern Time on January 30, 2025.

Dated: December 31, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2025–00090 Filed 1–6–25; 8:45 am]

BILLING CODE 6717–01–P

[6] 18 CFR 385.102(d).

[7] 18 CFR 385.214.

[8] 18 CFR 157.10.

[9] The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

[10] 18 CFR 385.214(c)(1).

[11] 18 CFR 385.214(b)(3) and (d).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2425–057]

PE Hydro Generation, LLC; Notice of Intent To Prepare an Environmental Assessment

On January 3, 2022, the PE Hydro Generation, LLC filed a new major license application for the 1,600-kilowatt (kW) Luray and 1,400-kW Newport Hydroelectric Project No. 2425 (project). The two-development Luray and Newport Project is located on the South Fork of the Shenandoah River near the Towns of Luray (Luray Development) and Newport (Newport Development) in Page County, Virginia.

In accordance with the Commission's regulations, on October 18, 2024, Commission staff issued a notice that the project was ready for environmental analysis (REA Notice). Based on the information in the record, staff does not anticipate that licensing the project would constitute a major Federal action significantly affecting the quality of the human environment. Therefore, staff intends to prepare an Environmental Assessment (EA) on the application to license the project.[1]

The EA will be issued and circulated for review by all interested parties. All comments filed on the EA will be analyzed by staff and considered in the Commission's final licensing decision.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members, and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

[1] In accordance with the Council on Environmental Quality's regulations, the unique identification number for documents relating to this environmental review is EAXX–019–20–000–1734604406. 40 CFR 1501.5(c)(4) (2024).

The application will be processed according to the following schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Commission issues EA	December 31, 2025.

Any questions regarding this notice may be directed to Kristine Sillett at (202) 502–6575 or *kristine.sillett@ferc.gov.*

Dated: December 31, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2025–00088 Filed 1–6–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2509–051]

PE Hydro Generation, LLC; Notice of Intent To Prepare an Environmental Assessment

On January 3, 2022, the PE Hydro Generation, LLC filed a subsequent minor license application for the 862-kilowatt Shenandoah Hydroelectric Project No. 2509 (project). The project is located on the South Fork of the Shenandoah River near the Town of Shenandoah in Page and Rockingham, Counties, Virginia.

In accordance with the Commission's regulations, on October 18, 2024, Commission staff issued a notice that the project was ready for environmental analysis (REA Notice). Based on the information in the record, staff does not anticipate that licensing the project would constitute a major Federal action significantly affecting the quality of the human environment. Therefore, staff intends to prepare an Environmental Assessment (EA) on the application to license the project.[1]

The EA will be issued and circulated for review by all interested parties. All comments filed on the EA will be analyzed by staff and considered in the Commission's final licensing decision.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members, and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

The application will be processed according to the following schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Commission issues EA	December 31, 2025.

Any questions regarding this notice may be directed to Kristine Sillett at (202) 502–6575 or *kristine.sillett@ferc.gov.*

Dated: December 31, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2025–00086 Filed 1–6–25; 8:45 am]

BILLING CODE 6717–01–P

[1] In accordance with the Council on Environmental Quality's regulations, the unique identification number for documents relating to this environmental review is EAXX–019–20–000–1734604304. 40 CFR 1501.5(c)(4) (2024).

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2018–0504; FRL–12481–01–OCSPP]

Dicyclohexyl phthalate (DCHP); Draft Risk Evaluation Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is announcing the availability of and seeking public comment on a draft risk evaluation under the Toxic Substances Control Act (TSCA) for Dicyclohexyl phthalate (DCHP) (1,2-benzenedicarboxylic acid, 1,2-dicyclohexyl ester) (CASRN 84–61–7). The purpose of risk evaluations under TSCA is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by EPA, under the conditions of use. EPA has used the best available science to prepare this draft risk evaluation and to preliminarily determine that DCHP poses unreasonable risk to human health.

DATES: Comments must be received on or before March 10, 2025.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2018–0504, online at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

Chemical specific information: Claire Brisse, Existing Chemical Risk Management Division (7404M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–9004; email address: *brisse.claire@epa.gov.*

General information: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave. Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This action is directed to the public in general and may be of particular interest to those involved in the manufacture, processing, distribution, use, and disposal of the chemical being evaluated, related industry trade organizations, non-governmental organizations with an interest in human and environmental health, state and local governments, Tribal Nations, and/or those interested in the assessment of risks involving chemical substances and mixtures regulated under TSCA. As such, the Agency has not attempted to describe all the specific entities that this action might apply to. If you need help determining applicability, consult the technical contact listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

The Agency is conducting this risk evaluation under TSCA section 6, 15 U.S.C. 2605, which requires that EPA conduct risk evaluations on chemical substances and identifies the minimum components EPA must include in all chemical substance risk evaluations. Each risk evaluation must be conducted consistent with the best available science, be based on the weight of the scientific evidence, and consider reasonably available information.

15 U.S.C. 2625(h), (i), and (k). See also the implementing procedural regulations at 40 CFR part 702. For more information about the TSCA risk evaluation process for existing chemicals, go to *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca.*

C. What action is the Agency taking?

EPA is announcing the availability of and seeking public comment on a draft risk evaluation under TSCA for DCHP (CASRN 84–61–7). The purpose of risk evaluations under TSCA is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or non-risk factors, including unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by EPA, under the conditions of use. This draft risk evaluation is consistent with the best available science, based on the weight of scientific evidence, and considers reasonably available information. EPA has preliminarily determined that DCHP poses unreasonable risk to human health.

D. What should I consider as I prepare my comments?

1. *Submitting CBI.*

Do not submit CBI to EPA through *https://www.regulations.gov* or email. If you wish to include CBI in your comment, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the information that you claim to be CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR parts 2 and 703, as applicable.

2. *Tips for preparing your comments.*

When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. Background

A. What is DCHP?

DCHP is a common chemical name for the chemical substance 1,2-benzenedicarboxylic acid, 1,2-dicyclohexyl ester (CASRN 84–61–7). DCHP is a granular solid at room temperature that is produced by the esterification of phthalic anhydride with cyclohexanols. It is primarily used as a plasticizer in adhesives and plastic and rubber products and resins for consumer, commercial, and industrial applications.

B. Why is EPA evaluating this chemical under TSCA?

In December 2019, EPA announced its designation of DCHP as a high-priority substance for risk evaluation under TSCA (Ref. 1). A draft scope of the DCHP risk evaluation was published in April 2020 (Ref. 2), and after receiving public comment, EPA issued the final scope of the DCHP risk evaluation in September 2020 (Ref. 3).

The Agency has evaluated the health and environmental risks of DCHP under TSCA section 6. Laboratory animal data suggest that developmental toxicity, specifically androgen insufficiency (phthalate syndrome), is the most sensitive and robust non-cancer hazard for DCHP. The Agency included DCHP for cumulative risk assessment along with five other phthalate chemicals that also cause effects on laboratory animals consistent with phthalate syndrome (Ref. 4). Notably, assessments by Health Canada, U.S. CPSC, European Chemicals Agency (ECHA), and the Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS) have reached similar conclusions regarding the effects of DCHP on development and have also conducted cumulative risk assessments of phthalates based on these chemicals' shared ability to cause phthalate syndrome. Further, independent, expert peer reviewers endorsed EPA's proposal to conduct a cumulative risk assessment of phthalates under TSCA during the May 2023 meeting of the Science Advisory Committee on Chemicals (SACC) because doing so represents the best available science. In this draft risk evaluation, EPA has evaluated cumulative exposure to phthalates for the U.S. civilian population using human biomonitoring data. These phthalate exposures to the general U.S. civilian population cannot be attributed to specific conditions of use or other sources. This non-attributable cumulative exposure and risk, representing that of the national population, was taken into consideration by EPA in reaching its preliminary determination of unreasonable risk of injury of human health for DCHP. Had EPA not taken this into consideration, it could have understated the unreasonable risk of injury to human health for DCHP.

In this draft risk evaluation, EPA has preliminarily determined that DCHP presents an unreasonable risk of injury to human health under the conditions of use (COUs). Of the 24 COUs that EPA evaluated, 9 COUs have risk estimates that raise concerns for workers' exposure to DCHP, and no COUs that raise such concerns for consumers or the general population. In its draft evaluation, EPA's protective, screening-level approaches demonstrated that DCHP does not pose risk to the environment.

After this draft risk evaluation is informed by public comment and independent, expert peer review advice, EPA will issue a final risk evaluation that includes its determination as to whether DCHP presents unreasonable risk to health or the environment under the TSCA COUs. EPA also continues to work on the draft risk evaluations of five additional high-priority chemical substance phthalates.

III. Request for Comment

EPA seeks feedback on the assessment of risk presented in the draft risk evaluation, a copy of which is available in the docket, and encourages all potentially interested parties, including individuals, governmental and non-governmental organizations, non-profit organizations, academic institutions, research institutions, and private sector entities to comment on the draft risk evaluation. To the extent possible, the Agency asks commenters to please cite any public data related to or that supports comments, and to the extent permissible, describe any supporting data that is not publicly available.

IV. Next Steps

In its risk evaluation, EPA must determine whether the chemical presents an unreasonable risk to health or the environment under the chemical's conditions of use. These factors include risks to subpopulations who may be at greater exposure or susceptibility than the general population, such as children and workers. TSCA prohibits EPA from considering non-risk factors (*e.g.,* costs/benefits) in making its risk determination.

If EPA determines that a chemical substance presents an unreasonable risk to health or the environment, the chemical substance must immediately move to risk management rulemaking action under TSCA. At the risk management stage, EPA is required to implement, via regulation, regulatory restrictions on the manufacture, processing, distribution, use or disposal so the chemical substance no longer presents an unreasonable risk. EPA is given a range of risk management options under TSCA, including labeling, recordkeeping or notice requirements, actions to reduce human exposure or environmental release, and a ban of the chemical substance or of certain uses. Like the prioritization and risk

evaluation processes, there is an opportunity for public comment on any proposed risk management actions.

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA) and Initiation of Risk Evaluation on High-Priority Substances; Notice of Availability. **Federal Register**. 84 FR 71924, December 30, 2019 (FRL–10003–15).

2. EPA. Draft Scopes of the Risk Evaluations To Be Conducted for Seven Chemical Substances Under the Toxic Substances Control Act; Notice of Availability. **Federal Register**. 85 FR 22733, April 23, 2020 (FRL–10008–05).

3. EPA. Final Scopes of the Risk Evaluations To Be Conducted for Twenty Chemical Substances Under the Toxic Substances Control Act; Notice of Availability. **Federal Register**. 85 FR 55281, September 4, 2020 (FRL–10013–90).

4. EPA. Cumulative Risk Assessment Under the Toxic Substances Control Act. EPA website at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/cumulative-risk-assessment-under-toxic-substances#.*

Authority: 15 U.S.C. 2601 *et seq.*

Dated: December 30, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2025–00137 Filed 1–6–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2024–0061; FRL–11680–11–OCSPP]

Pesticide Product Registration; Receipt of Applications for New Uses (November 2024)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before February 6, 2025.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2024–0061, through the *Federal eRulemaking Portal* at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Madison H. Le, Biopesticides and Pollution Prevention Division (BPPD) (7511M), main telephone number: (202) 566–1400, email address: *BPPDFRNotices@epa.gov.* The mailing address for each contact person is Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. Registration Applications

EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications.

Notice of Receipt—New Uses

EPA Registration Number: 88847–7. *Docket ID number:* EPA–HQ–OPP–2024–0576. *Applicant:* Vestaron Corporation, 4025 Stirrup Creek Drive, Suite 400, Durham, NC 27703 USA. *Active ingredient:* U1-AGTX-Ta1b-qa. *Product type:* Insecticide. *Proposed use:* Outdoor Terrestrial Use. *Contact:* BPPD.

Authority: 7 U.S.C. 136 *et seq.*

Dated: December 19, 2024.

Kimberly Smith,

Acting Director, Information Technology and Resources Management Division, Office of Program Support.

[FR Doc. 2025–00096 Filed 1–6–25; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION

[Docket No. FMC–2024–0025]

Policy Statement on Class Action Complaints

AGENCY: Federal Maritime Commission.

ACTION: Notice of availability.

SUMMARY: The Federal Maritime Commission (Commission) is issuing this document to advise the public of the availability of a new policy statement. The policy statement explains that private parties are not precluded from bringing class action complaints at the Commission.

DATES: Policy statement *On Class Action Complaints* announced in this document was issued on January 2, 2025.

ADDRESSES: The policy statement can be found at the following link: *https://www2.fmc.gov/readingroom/proceeding/24-29/.*

FOR FURTHER INFORMATION CONTACT: David Eng, Secretary; Phone: (202) 523–5725; Email: *Secretary@fmc.gov.*

SUPPLEMENTARY INFORMATION: On January 2, 2025, the Commission issued a policy statement to provide guidance to shippers and other third parties on bringing class action complaints at the Commission. As the policy statement explains, class action complaints are not precluded by Title 46 or the Commission's interpretation of the statute. In accordance with 46 CFR 502.12, the Commission may follow the Federal Rules of Civil Procedure ''for situations which are not covered by a specific Commission rule . . . to the extent that they are consistent with sound administrative practice.'' The Commission may use the procedures of Rule 23 of the Federal Rules of Civil Procedure to evaluate class action complaints filed with the Commission because the requirements under § 502.12 are satisfied.

The policy statement can be found at the following link: *https://www2.fmc.gov/readingroom/proceeding/24-29/.*

This document is issued under authority of 5 U.S.C. 552, 46 U.S.C. 46105 and 46 CFR 502.12.

By the Commission.

David Eng,

Secretary.

[FR Doc. 2025–00074 Filed 1–6–25; 8:45 am]

BILLING CODE 6730–02–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 January 22, 2025.

A. Federal Reserve Bank of Atlanta (Erien O. Terry, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *Linda M. Young and Nathaniel J. Pierson, both of Fort Payne, Alabama, and Chris Y. Pierson, Valley Head, Alabama;* to join the Young Family Control Group, a group acting in concert, to retain voting shares of FBDC Financial Corp., and thereby indirectly retain voting shares of First Fidelity Bank, both of Fort Payne, Alabama.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2025–00075 Filed 1–6–25; 8:45 am]

BILLING CODE P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Extension

AGENCY: Federal Trade Commission.

ACTION: Notice.

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission'') requests that the Office of Management and Budget (''OMB'') extend for an additional three years the current Paperwork Reduction Act (''PRA'') clearance for information collection requirements contained in the Red Flags, Card Issuers, and Address Discrepancy Rules (''Rules''). That clearance expires on January 31, 2025.

DATES: Comments must be filed by February 6, 2025.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Whitney Moore, Attorney, Division of Division of Privacy and Identity Protection, Bureau of Consumer Protection, Federal Trade Commission, Mail Code CC–8232, 600 Pennsylvania Avenue NW, Washington, DC 20580, (202) 326–2645.

SUPPLEMENTARY INFORMATION:

A. Background and Comments

The FTC's Office of Management and Budget (''OMB'') clearance (OMB Control No.: 3084–0137) for the collection of information under the Red Flags, Card Issuers, and Address Discrepancy Rules (''Rules''),[1] which implement sections 114 and 315 of the Fair and Accurate Credit Transactions Act of 2003 (''FACT Act''), as amended by the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act'') [2] and the Red Flags Program Clarification Act of 2010 (''Clarification Act''),[3] is set to expire on January 31, 2025. Accordingly, on August 22, 2024, the Commission published a **Federal Register** Notice seeking public comment on the proposal to renew this OMB clearance for an additional three-year period. *See* 89 FR 67938 (Aug. 22, 2024). In response to the **Federal Register** Notice, the Commission received two germane comments.

The two comments were generally supportive of the information collection, although the two commenters indicated that they believe that the federal government's efforts in the context of personal data protections should be expanded.[4] The Commission thanks the commenters for their submissions, and notes that the Commission has also

[1] Red Flags Rule, 16 CFR 681.1; Card Issuers Rule, 16 CFR 681.2; Address Discrepancy Rule, 16 CFR part 641.

[2] Public Law 111–203 (2010).

[3] Red Flag Program Clarification Act of 2010, 15 U.S.C. 1681m(e)(4).

[4] *See https://www.regulations.gov/comment/FTC-2022-0010-0004; https://www.regulations.gov/comment/FTC-2022-0010-0003.*

supported greater personal data protections for American consumers by, among other things, encouraging Congress to enact comprehensive federal privacy legislation.[5] However, such initiatives would be beyond the scope of this PRA renewal request. Accordingly, for the foregoing reasons, the Commission declines to make any adjustments to its prior burden estimates or to modify its initial proposal.

B. Overview of Information Collection

Title of Collection: Red Flags Rule, 16 CFR 681.1; Card Issuers Rule, 16 CFR 681.2; Address Discrepancy Rule, 16 CFR part 641.

OMB Control Number: 3084–0137.

Type of Review: Extension of currently approved collection.

Abstract: The Red Flags Rule requires financial institutions and certain creditors to develop and implement written Identity Theft Prevention Programs. The Card Issuers Rule requires credit and debit card issuers to assess the validity of notifications of address changes under certain circumstances. The Address Discrepancy Rule provides guidance on what covered users of consumer reports must do when they receive a notice of address discrepancy from a nationwide consumer reporting agency. Collectively, these three anti-identity theft provisions are intended to prevent impostors from misusing another person's personal information for a fraudulent purpose. The Rules implement sections 114 and 315 of the FACT Act.

Affected Public

Red Flags Rule: Utilities; motor vehicle dealerships; telecommunications firms; colleges and universities; hospitals; nursing homes; public warehouse and storage firms; fuel dealers; financial transaction processing firms; certain creditors;[6] and other categories of persons that qualify as financial institutions.

Card Issuers Rule: State-chartered credit unions; general merchandise stores; colleges and universities; telecommunications firms; and certain creditors.[7]

Address Discrepancy Rule: Users of consumer reports that are motor vehicle dealers described in section 1029(a) of the Dodd-Frank Act, 12 U.S.C. 5519, and that are predominantly engaged in the sale and servicing of motor vehicles, the leasing and servicing of them, or both.

Estimated Number of Respondents: 238,942 (165,494 for Red Flags Rule + 18,500 for Card Issuers Rule + 54,948 for Address Discrepancy Rule).

Estimated Annual Burden Hours: 398,479 hours (358,124 hours for Red Flags Rule + 18,608 hours for Card Issuers Rule + 21,747 hours for Address Discrepancy Rule).

Estimated Annual Labor Costs: $22,350,652 ($21,850,471 for Red Flags and Card Issuers Rule + $500,181 for Address Discrepancy Rule).

Estimated Annual Non-Labor Costs: $0.

C. Request for Comment

On August 22, 2024, the FTC sought public comment on the information collection requirements associated with the Rules. 89 FR 67938 (Aug. 22, 2024). Two germane comments were received during the first public comment period and are addressed above. Pursuant to OMB regulations, 5 CFR part 1320, that implement the PRA, 44 U.S.C. 3501 *et seq.,* the FTC is providing this second opportunity for public comment while seeking OMB approval to renew the pre-existing clearance for the Rules. For more details about the Rules' requirements and the basis for the calculations summarized above, see 89 FR 67938.

Your comment—including your name and your state—will be placed on the public record of this proceeding. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as anyone's Social Security number; date of birth; driver's license number or other state identification number or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for ensuring that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''[t]rade secret or any commercial or financial information which is . . . privileged or confidential''—as provided in section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including, in particular, competitively sensitive information, such as costs, sales statistics, inventories, formulas, patterns devices, manufacturing processes, or customer names.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

[FR Doc. 2025–00008 Filed 1–6–25; 8:45 am]

BILLING CODE 6750–01–P

[5] *See, e.g.,* A Look Behind the Screens: Examining the Data Practices of Social Media and Video Streaming Services (Sept. 11, 2024), *https://www.ftc.gov/system/files/ftc_gov/pdf/Social-Media-6b-Report-9-11-2024.pdf* (recommending that Congress enact comprehensive federal privacy legislation that limits surveillance and grants consumers data rights).

[6] 15 U.S.C. 1681m(e)(4).

[7] *Id.*

GOVERNMENT ACCOUNTABILITY OFFICE

Request for Medicare Payment Advisory Commission (MedPAC) Nominations

AGENCY: Government Accountability Office.

ACTION: Request for letters of nomination and resumes.

SUMMARY: The Balanced Budget Act of 1997 established the Medicare Payment Advisory Commission (MedPAC) and gave the Comptroller General of the United States responsibility for appointing its members. The Government Accountability Office (GAO) is now accepting nominations for MedPAC appointments that will be effective in May 2025. Nominations should be sent to the email address listed below. Acknowledgement of receipt will be provided within a week of submission.

DATES: Letters of nomination and resumes should be submitted no later than February 7, 2025, to ensure adequate opportunity for review and consideration of nominees prior to appointment.

ADDRESSES: Submit letters of nomination and resumes to *MedPACappointments@gao.gov.*

FOR FURTHER INFORMATION CONTACT: Greg Giusto at *giustog@gao.gov* or (202) 512–7114 if you do not receive an acknowledgement or need additional information. For general information, contact GAO's Office of Public Affairs, at *PublicAffairs@gao.gov.*

Authority: 42 U.S.C. 1395b–6.

Gene L. Dodaro,

Comptroller General of the United States.

[FR Doc. 2024–30290 Filed 1–6–25; 8:45 am]

BILLING CODE 1610–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–65 and CMS–10142]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Correction

In notice document 2024–30444 beginning in the third column on page 104182 in the issue of Friday, December 20, 2024, make the following correction:

On page 104182, in the third column, under the **DATES** section, replace the text [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**] with ''January 21, 2025''.

[FR Doc. C1–2024–30444 Filed 1–6–25; 8:45 am]

BILLING CODE 0099–10–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Refugee Resettlement

Statement of Organization, Functions, and Delegations of Authority; Delegation From Office of Refugee Resettlement Director to Unaccompanied Children Bureau Chief

Notice is hereby given that I delegate to the Chief of the Unaccompanied Children Bureau the following authority delegated to the Deputy Assistant Secretary for Humanitarian Services and Director of the Office of Refugee Resettlement by the Assistant Secretary for Children and Families and the Secretary under the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (Pub. L. 110–457 sec. 235, amended).

(a) Authority Delegated

Authority under the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 section 235(d)(1) to specifically consent to juvenile court jurisdiction for an unaccompanied alien child who is applying for special immigrant status pursuant to the Immigration and Nationality Act (8 U.S.C. 1101 (a)(27)(J)) and who is in the custody of the Secretary.

(b) Limitations

1. This delegation shall be exercised under the Department's existing delegation of authority and policy on regulations.

2. This delegation shall be exercised under financial and administrative requirements applicable to all Administration for Children and Families authorities.

(c) Effective Date

This delegation of authority is effective on date of signature. In addition, I hereby affirm and ratify any actions taken by the Chief of the Unaccompanied Children Bureau, which, in effect, involved the exercise of these authorities prior to the effective date of this delegation.

Robin Dunn Marcos,

Deputy Assistant Secretary for Humanitarian Services and Director, Office of Refugee Resettlement.

[FR Doc. 2025–00004 Filed 1–6–25; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3539]

Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' This guidance describes FDA's interim regulatory policy concerning compounding by outsourcing facilities using bulk drug substances while FDA develops the list of bulk drug substances that outsourcing facilities can use in compounding under the applicable section of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance finalizes the draft guidance of the same title issued in December 2023 and replaces the final guidance of the same title issued in January 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on January 7, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–3539 for ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the

information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Rechelle Buford, Center for Drug Evaluation and Research, 10903 New Hampshire Ave, Bldg., 51, Silver Spring, MD 20993–0002, 240–402–0447, *compounding@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act'' (2024 503B Interim Policy Guidance). This guidance finalizes the draft guidance entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act'' issued on December 7, 2023 (88 FR 85293), and replaces the guidance of the same title issued in January 2017 (2017 503B Interim Policy Guidance).

Section 503B of the FD&C Act (21 U.S.C. 353b) sets forth the conditions that must be satisfied for human drug products compounded by an outsourcing facility to be exempt from the following three sections of the FD&C Act: (1) section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 582 (21 U.S.C. 360eee–1) (concerning drug supply chain security requirements). One of the conditions that must be met for a drug product compounded by an outsourcing facility to qualify for these exemptions is that the outsourcing facility does not compound a drug using a bulk drug substance unless: (1) the bulk drug substance appears on a list established by the Secretary of the Department of Health and Human Services identifying bulk drug substances for which there is a clinical need (the 503B bulks list) (see section 503B(a)(2)(A)(i)) or (2) the drug product compounded from such bulk drug substances appears on the drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e) at the time of compounding, distribution, and dispensing (see section 503B(a)(2)(A)(ii) of the FD&C Act).

FDA is developing the 503B bulks list, and this guidance describes FDA's interim policy regarding outsourcing facilities that compound human drug products using bulk drug substances while the list is being developed. This guidance revises the policy described in FDA's 2017 503B Interim Policy Guidance with respect to categorization of certain substances nominated for inclusion on the 503B bulks list. This guidance ends the categorization of bulk drug substances into Categories 1, 2, or 3 for those bulk drug substances nominated on or after the date of publication of this guidance.

The 2024 503B Interim Policy Guidance describes the conditions under which FDA does not intend to take action against an outsourcing facility for compounding a drug product using certain bulk drug substances that are not eligible for use in compounding under section 503B of the FD&C Act because they do not appear on the 503B bulks list and are not used to compound a drug product that appears on FDA's drug shortage list at the time of compounding, distribution, and dispensing. One of these conditions is that the bulk drug substance appears in Category 1. As described in this guidance, FDA does not intend to categorize bulk drug substances nominated for inclusion on the 503B bulks list on or after the publication date of this guidance. However, FDA intends to consider such substances for inclusion on the 503B bulks list in accordance with the process and clinical need standard established in the FD&C Act (see section 503B(a)(2)(A)(i) of the FD&C Act). FDA is evaluating bulk drug substances nominated for the 503B bulks list on a rolling basis. Substances that appear in Category 1 (including substances nominated with adequate supporting information prior to the date of publication of this guidance) may continue to be within the scope of the policy for Category 1 substances, as described in the guidance, until FDA makes a final determination whether these substances will be placed on the 503B bulks list in accordance with section 503B(a)(2)(A)(i) of the FD&C Act or unless the Agency removes the substances from Category 1 based on, for example, information about safety risks.

Prior to preparing this guidance, FDA considered comments received on the draft guidance. Editorial changes were made to improve clarity, such as updating references to the publication date of this final guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either

https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or *https://www.regulations.gov.*

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31545 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–4245]

Study of Sex Differences in the Clinical Evaluation of Medical Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Study of Sex Differences in the Clinical Evaluation of Medical Products.'' Clinical trials and non-interventional studies of medical products should be designed to enroll sufficient numbers of females and males to reflect the prevalence of the disease or condition for which the medical product is being investigated to help ensure the generalizability of results and facilitate exploration of potential differences in effects by sex. This guidance provides recommendations for increasing enrollment of females in clinical trials, analyzing and interpreting sex-specific data, and including sex-specific information in regulatory submissions of medical products. When finalized, this guidance will replace the guidance entitled ''Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs'' issued in July 1993.

DATES: Submit either electronic or written comments on the draft guidance by April 7, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–4245 for ''Study of Sex Differences in the Clinical Evaluation of Medical Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; the Office of Policy, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or the Office of Women's Health, 10903 New Hampshire Ave., Bldg. 32, Rm. 2333, Silver Spring, 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993–0002, 240–402–8926, *Dat.Doan@fda.hhs.gov;* James Myers, Center for Biologics Evaluation and

Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; Terri Cornelison, Center for Devices and Radiological Health,10903 New Hampshire Ave., Bldg. 66, Rm. 5516, Silver Spring, MD 20993–0002, 301–796–5682; or Office of Women's Health, 10903 New Hampshire Ave., Bldg. 32, Rm. 2333, Silver Spring, MD 20993–0002, *FDA-OWH@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Study of Sex Differences in the Clinical Evaluation of Medical Products.'' Analyzing sex-related differences in medical product response is an important component of assessing product safety and effectiveness, to help understand safety and effectiveness across the intended patient population, and can inform what goes into product labeling to improve patient care. Differences in physiology between females and males can lead to differences in disease manifestation, pharmacokinetics, pharmacodynamics, and response to treatment, among other things. Topics addressed in this guidance include: (1) practices to improve the recruitment, enrollment, and retention of females in clinical trials, to help ensure the generalizability of research results to intended patient populations; (2) statistical considerations for analyzing sex differences; and (3) reporting results based on analyses of sex differences.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Study of Sex Differences in the Clinical Evaluation of Medical Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 26, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31537 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0099]

Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a revised final guidance for industry entitled ''Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Guidance for Industry.'' The guidance explains FDA's current thinking on a number of issues related to the labeling of food allergens, including requirements in the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) and the Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER Act).

DATES: The announcement of the guidance is published in the **Federal Register** on January 7, 2025.

ADDRESSES: You may submit either electronic or written comments on FDA guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–0099 for ''Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the

Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Nutrition and Food Labeling, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Carol D'Lima, Office of Nutrition and Food Labeling (HFS–800), Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371; or Denise See, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Guidance for Industry.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

FALCPA (Pub. L. 108–282) was enacted in August 2004 and, in part, amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by defining the term ''major food allergen'' and requiring that the presence of any major food allergen be declared on the labels of FDA-regulated foods. FALCPA defined a major food allergen as milk, egg, fish (*e.g.,* bass, flounder, or cod), Crustacean shellfish (*e.g.,* crab, lobster, or shrimp), tree nuts (*e.g.,* almonds, pecans, or walnuts), wheat, peanuts, and soybeans and as a food ingredient that contains protein derived from these foods (section 201(qq) of the FD&C Act (21 U.S.C. 321(qq))). In addition, the FASTER Act (Pub. L. 117–11) was enacted in April 2021 and, in part, amended the definition of major food allergen in the FD&C Act to include sesame.

Since the passage of FALCPA, FDA has received numerous questions about food allergen labeling requirements. To explain FALCPA's requirements as well as FDA's current thinking on issues relating to the regulation of food allergens, on October 5, 2005, FDA issued the first edition of a guidance entitled ''Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004.'' We subsequently updated the guidance in December 2005 (Edition 2), April 2006 (Edition 3), and October 2006 (Edition 4).

In the **Federal Register** of November 30, 2022 (87 FR 73561), FDA issued a draft guidance for industry entitled ''Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5).'' The draft guidance was a revision of Edition 4 originally entitled ''Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004'' that contained revised and new questions and answers relating to food allergens, including questions and answers about FALCPA and the FASTER Act. We gave interested parties an opportunity to submit comments for us to consider before beginning work on the final version of the guidance. We received numerous comments on the draft guidance and have made modifications in this final guidance where appropriate. On November 30, 2022, FDA also issued a final guidance, ''Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5),'' that contained the questions and answers from Edition 4 that remained unchanged, with the exception of editorial changes such as renumbering and organizational changes, and therefore were reissued as final guidance. The revised final guidance announced in this notice consolidates both the draft and final guidance that issued on November 30, 2022.

The revised final guidance contains questions and answers about food allergen labeling requirements, including the labeling of sesame, milk, eggs, incidental additives, highly refined oils, dietary supplement products, and certain specific packing and labeling situations (*e.g.,* individual units within a multiunit package). We have made some changes from the draft guidance. For example, we have expanded our historical interpretation of the terms ''milk'' and ''eggs;'' for purposes of the definition of a ''major food allergen'' under section 201(qq) of the FD&C Act and for purposes of complying with the food allergen labeling requirements of the FD&C Act. FDA has historically interpreted ''milk'' as milk from the domesticated cow and ''eggs'' as eggs from the domesticated chicken. However, the final guidance sets forth that for purposes of the definition of a ''major food allergen'' under section 201(qq) of the FD&C Act, FDA considers ''milk'' as milk from domesticated cows, goats, sheep, or other ruminants and FDA considers ''eggs'' as eggs from domesticated chickens, ducks, geese, quail, and other fowl. In addition, the final guidance

revises the list of tree nuts that FDA considers as major food allergens.

We also have revised several questions and answers to update and clarify information presented in previous editions, including questions related to the labeling of fish and Crustacean shellfish.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in section 403(w) of the FD&C Act (21 U.S.C. 343(w)) have been approved under OMB control number 0910–0792.

III. Electronic Access

Persons with access to the internet may obtain the guidance document at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/FoodGuidances,* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31533 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0278]

Action Levels for Lead in Processed Food Intended for Babies and Young Children; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry entitled ''Action Levels for Lead in Processed Food Intended for Babies and Young Children.'' The guidance establishes action levels for lead in certain processed foods intended for babies and young children less than 2 years old. The guidance is intended to set achievable action levels that will help further reduce lead in the food supply.

DATES: The announcement of the guidance is published in the **Federal Register** on January 7, 2025.

ADDRESSES: You may submit either electronic or written comments on FDA guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–0278 for ''Action Levels for Lead in Processed Food Intended for Babies and Young Children; Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Eileen Abt, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1700; or Holli Kubicki, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug

Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Action Levels for Lead in Processed Food Intended for Babies and Young Children.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of January 25, 2023 (88 FR 4749), we made available a draft guidance for industry entitled ''Action Levels for Lead in Food Intended for Babies and Young Children'' and gave interested parties an opportunity to submit comments by March 27, 2023, for us to consider before beginning work on the final version of the guidance. In the **Federal Register** of April 6, 2023 (88 FR 20525), we announced that we were reopening the comment period until May 8, 2023, to allow interested parties additional time to submit comments. We received several comments on the draft guidance and have modified the final guidance where appropriate. Changes to the guidance include clarifications to the foods that the guidance addresses, including the age range of the foods' intended consumers. We added information about the method that FDA uses to test for lead in food and made several editorial changes to improve clarity of the guidance. We also collected and analyzed additional samples from our Toxic Elements Program and special FDA surveys to inform our exposure and achievability assessments. The guidance announced in this notice finalizes the draft guidance dated January 2023.

In accordance with § 109.6 (21 CFR 109.6), this guidance establishes the following action levels for lead in processed food intended for babies and young children less than 2 years old: 10 parts per billion (ppb) for fruits, vegetables (excluding single-ingredient root vegetables), mixtures (including grain- and meat-based mixtures), yogurts, custards/puddings, and single-ingredient meats; 20 ppb for single-ingredient root vegetables; and 20 ppb for dry infant cereals. Consistent with § 109.6(d), these action levels reflect levels of lead at which FDA may regard the food as adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1)). We intend to consider these action levels, in addition to other factors, when considering whether to bring enforcement action in a particular case.

II. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/FoodGuidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31534 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3517]

Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act.'' This guidance describes FDA's interim policy concerning compounding by human drug product compounders that are not outsourcing facilities using bulk drug substances while FDA develops the list of bulk drug substances that can be used in compounding under the applicable section of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance finalizes the draft guidance of the same title issued in December 2023 and replaces the final guidance of the same title issued in January 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on January 7, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–3517 for ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Mariestela Buhay, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993–0002, 301–796–7313, *Compounding@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act'' (2024 503A Interim Policy Guidance). This guidance finalizes the draft guidance entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act'' issued on December 7, 2023 (88 FR 85296), and replaces the guidance of the same title issued in January 2017 (2017 503A Interim Policy Guidance).

Section 503A of the FD&C Act (21 U.S.C. 353a) sets forth the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to be exempt from the following three sections of the FD&C Act: (1) section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice requirements). One of the conditions that must be met for a compounded drug product to qualify for these exemptions is that a licensed pharmacist or licensed physician compounds the drug product using bulk drug substances that (1) comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapters on pharmacy compounding; (2) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary of the Department of Health and Human Services (Secretary); or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appears on a list developed by the Secretary through regulations issued by the Secretary under subsection (c) of section 503A of the FD&C Act (the 503A bulks list). (See section 503A(b)(1)(A)(i) of the FD&C Act.)

FDA is developing the 503A bulks list, and this guidance describes FDA's interim policy for licensed pharmacists in State-licensed pharmacies and Federal facilities and for licensed physicians who compound human drug products using bulk drug substances while the list is being developed. This guidance revises the policy described in FDA's 2017 503A Interim Policy Guidance with respect to categorization of certain substances nominated for inclusion on the 503A bulks list. This guidance ends the categorization of bulk drug substances into Categories 1, 2, or 3 for those bulk drug substances nominated on or after the date of publication of this guidance.

The 2024 503A Interim Policy Guidance describes the conditions under which FDA does not intend to take action against a State-licensed pharmacy, Federal facility, or physician for compounding drug products using certain bulk drug substances that are not eligible for use in compounding under section 503A of the FD&C Act because they are not the subject of an applicable USP or NF monograph, components of FDA-approved drug products, or on the 503A bulks list at § 216.23(a) (21 CFR 216.23(a)). One of these conditions is that the bulk drug substance appears in Category 1. As described in the guidance, FDA does not intend to categorize bulk drug substances nominated for inclusion on the 503A bulks list on or after the publication date of this guidance. However, FDA intends to consider such substances for inclusion on the 503A bulks list in accordance with the process and criteria established in the FD&C Act and FDA regulations (see section 503A(b)(1)(A) of the FD&C Act and § 216.23(c)). FDA is evaluating bulk drug substances nominated for the 503A bulks list on a rolling basis. Substances that appear in Category 1 (including substances nominated with adequate supporting information prior to the date of publication of this guidance) may continue to be within the scope of the policy that applies to Category 1 substances, as described in this guidance, until FDA promulgates a final rule determining whether they will be placed on the 503A bulks list in accordance with section 503A(b)(1)(A)(i)(III) of the FD&C Act or unless the Agency removes the substances from Category 1 based on, for example, information about safety risks.

Prior to preparing this guidance, FDA considered comments received on the draft guidance. Editorial changes were made to improve clarity, such as updating references to the publication date of this guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current

thinking of FDA on ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31546 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–2978]

Food and Drug Administration Animal Food Ingredient Consultation; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry #294 entitled ''Animal Food Ingredient Consultation (AFIC).'' This guidance describes FDA's interim AFIC process and explains one way FDA will work with firms that are developing animal food ingredients now that the Memorandum of Understanding (MOU) with the Association of American Feed Control Officials (AAFCO) expired on October 1, 2024, and while FDA evaluates the animal Food Additive Petition and Generally Recognized as Safe (GRAS) Notification programs. The AFIC process provides an additional way for engagement with FDA regarding ingredients for which firms may otherwise have used the AAFCO ingredient definition process. AFIC will help FDA identify any potential safety concerns associated with such ingredients. The AFIC process also allows for public awareness of and input on such ingredients. In addition, this guidance describes FDA's enforcement policy for certain ingredients assessed using the AFIC process.

DATES: The announcement of the guidance is published in the **Federal Register** on January 7, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–2978 for ''Animal Food Ingredient Consultation (AFIC).'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section

for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Charlotte Conway, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6768, *Charlotte.Conway@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 9, 2024 (89 FR 65368), FDA published the notice of availability for a draft guidance #294 entitled ''Animal Food Ingredient Consultation (AFIC),'' giving interested persons until September 9, 2024, to comment on the draft guidance. FDA received numerous comments on the draft guidance, including comments from the animal food and drug industries, AAFCO, a veterinary association, a State food and agriculture department, and private citizens, and those comments were considered as the guidance was finalized. In response to comments, the guidance was revised. First, we clarified the scope of the AFIC process as including any animal food ingredient for which firms may have otherwise utilized the AAFCO ingredient definition process. We also clarified that a proposed ingredient name and definition should be included in the consultation for FDA's consideration. We removed the recommendation to submit a statement of environmental risk. In addition, we clarified that firms participating in the AFIC process should not resubmit information they have already provided to FDA and added clarification regarding what information interested parties should include when providing comments on pending AFICs through the docket. Lastly, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated August 9, 2024.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Animal Food Ingredient Consultation (AFIC).'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. FDA is issuing this guidance, as final, that includes information collection recommendations regarding animal food ingredient consultations with FDA, which are subject to review and approval by OMB under the PRA. FDA will implement the information collection recommendations upon OMB approval and will announce OMB approval in the **Federal Register**. Information collection pertaining to animal food ingredient safety is currently provided for in FDA regulations in 21 CFR parts 570 and 571, currently approved in OMB control numbers 0910–0342 and 0910–0546, respectively. Disclosures under 21 CFR 501.22 requiring animal food manufacturers to declare the presence of certified and noncertified color additives in animal food product labeling are also currently approved in OMB control number 0910–0546. However, upon our review of the latter information collection, we note that while we account for general reporting activities applicable to animal food ingredient regulations, we do not discuss activities that may be specifically attributable to animal food ingredient consultations with FDA. We also acknowledge that discontinuation of the MOU with AAFCO may result in an adjustment for some respondents with regard to how they engage in consultation with FDA. On December 19, 2024, FDA published a notice (89 FR 103838) under the PRA of its intent to revise the information collection to explicitly discuss animal food ingredient consultations that we believe are implicitly contemplated by the existing regulations in 21 CFR parts 570 and 571 specifically to invite comment on the associated burden.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov*.

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31525 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–1102]

Labeling of Plant-Based Alternatives to Animal-Derived Foods: Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled ''Labeling of Plant-Based Alternatives to Animal-Derived Foods.'' This draft guidance, when finalized, will provide our recommendations on best practices for naming and labeling of certain plant-based foods that are marketed and sold as alternatives for animal-derived foods (plant-based alternative foods), especially in the absence of a common or usual name for the product. This draft guidance does not address the naming and labeling of plant-based milk alternatives; FDA is providing recommendations regarding these products in a separate guidance document.

DATES: Submit either electronic or written comments on the draft guidance by May 7, 2025 to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by March 10, 2025.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note

that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–1102 for ''Labeling of Plant-Based Alternatives to Animal-Derived Foods: Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to Office of Nutrition and Food Labeling (HFS–800), Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance: Andrea Krause, Office of Nutrition and Food Labeling (HFS–820), Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371; or Lauren Kleinman, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

With regard to the proposed collection of information: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Labeling of Plant-Based Alternatives to Animal-Derived Foods.'' This draft guidance is intended to provide our recommendations on best practices for naming and labeling of certain plant-based foods that are marketed and sold as alternatives for animal-derived foods (plant-based alternative foods), especially in the absence of a common or usual name for the product. Consumer demand for plant-based alternative foods has increased and FDA is committed to helping ensure consumers understand the foods they buy, to help them make informed dietary choices. The scope of this draft guidance includes plant-based alternatives to eggs, seafood, poultry, meat, and dairy (excluding plant-based milk alternatives) that fall under FDA jurisdiction. (In the **Federal Register** of February 23, 2023 (88 FR 11449), we announced the availability of a draft guidance entitled ''Labeling of Plant-based Milk Alternatives and Voluntary Nutrient Statements: Draft Guidance for Industry.'' When finalized, the guidance will provide FDA's view on the naming of plant-based food products that are marketed and sold as alternatives to milk (plant-based milk alternatives) and our recommendations on the use of voluntary nutrient statements. The draft guidance entitled ''Labeling of Plant-based Milk Alternatives and Voluntary Nutrient Statements: Draft Guidance for Industry'' is available online at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-labeling-plant-based-milk-alternatives-and-voluntary-nutrient-statements.*)

We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Labeling of Plant-Based Alternatives to Animal-Derived Foods: Draft Guidance for Industry

OMB Control Number 0910–0381—Revision

The draft guidance, once finalized, will provide recommendations on best practices for naming and labeling of certain plant-based alternative foods. Industry's use of these recommendations for naming and labeling plant-based alternative foods will help ensure consumers understand the nature of individual plant-based alternative foods, including differences among these products, and have the information they need to make informed purchasing decisions.

Standards of identity have not been established for plant-based alternative foods. As such, plant-based alternative foods are non-standardized foods and must be labeled with their common or usual name, or in the absence thereof, a statement of identity that accurately describes the food. See 21 CFR 101.3(b). Many plant-based alternative foods are novel foods and do not have common or usual names established by common usage. Currently, products appear to be identified in multiple ways, sometimes inconsistently across the category. Thus, the purpose of this guidance is to provide our recommendations on best practices for naming and labeling of certain plant-based foods that are marketed and sold as alternatives for animal-derived foods.

Description of respondents: Respondents to this information collection are manufacturers, packers, and distributors of plant-based alternative foods that are marketed and sold in the United States. Respondents are from the private sector (for-profit businesses).

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED THIRD-PARTY DISCLOSURE BURDEN

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs [1] [2]
Labeling recommendations in ''Labeling of Plant-Based Alternatives to Animal-Derived Foods''	160	5	800	1	800	$1,231,200

[1] One-time relabeling costs.
[2] There are no operating and maintenance costs associated with this collection of information.

The estimates in table 1 are based on our experience with similar labeling programs. We estimate that each year 160 manufacturers will relabel their products following recommendations found in the draft guidance. We estimate that each manufacturer will relabel 5 products for 800 total annual disclosures (160 manufacturers × 5 labels). Each disclosure will take an estimated 1 hour to complete for an annual third-party disclosure burden of 800 hours (800 disclosures × 1 hour). We estimate that there will be an annual capital cost of $1,231,200 associated with relabeling. This is the cost of designing a revised label and incorporating it into the manufacturing process. We believe that this will be a one-time burden per respondent.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/FoodGuidances,* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31535 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–3067]

Recommendations To Reduce the Risk of Transmission of Disease Agents Associated With Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a final guidance for immediate implementation entitled ''Recommendations To Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' FDA is issuing this guidance to provide establishments making donor eligibility determinations with recommendations to reduce the risk of transmission of infections due to sepsis by HCT/Ps. This notice is being issued to respond to a public health safety concern and to address the urgent need for updated recommendations in making a donor eligibility determination when screening a donor for clinical evidence of sepsis and clinical signs to consider.

DATES: The announcement of the guidance is published in the **Federal Register** on January 7, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–3067 for ''Recommendations To Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive labels to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jessica Gillum, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for immediate implementation entitled ''Recommendations To Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).''

FDA is issuing the guidance to provide establishments making donor eligibility determinations with recommendations to reduce the risk of transmission of disease agents associated with sepsis for donors of human cells, tissues, and cellular and tissue-based products. This guidance supersedes the information regarding sepsis in the August 2007 guidance entitled ''Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' The August 2007 guidance identified sepsis as a relevant communicable disease agent or disease under 21 CFR 1271.3(r)(2).

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of another guidance for immediate implementation entitled ''Recommendations To Reduce the Risk of Transmission of *Mycobacterium Tuberculosis* (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' This guidance is being issued to assist establishments that make donor eligibility determinations for donors of human cells, tissues, and cellular and tissue-based products, with recommendations for screening donors for evidence of, and risk factors for, infection with Mtb, the organism that causes tuberculosis, which can be a cause of sepsis.

We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). We made this determination because of the urgent need to update recommendations to industry for screening a donor for risk factors and conditions, and clinical and physical evidence, associated with the disease agents that cause sepsis. Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA's GGP regulation.

The guidance represents the current thinking of FDA on ''Recommendations To Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR 1271 relating to HCT/Ps, including establishing and maintaining records, investigation and reporting of adverse actions and documentation of methods used in facilities related to HCT/Ps, which, includes but not limited to donor screening, donor testing, and labeling have been approved under OMB control number 0910–0543.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31538 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–5376]

Type VII Veterinary Master File for Research and Development and Risk Reviews; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry (GFI) #260 entitled ''Type VII Veterinary Master File for Research and Development and Risk Reviews.'' This draft guidance, when finalized, will describe FDA's current thinking regarding the use of Type VII Veterinary Master Files (Type VII VMFs). Type VII VMFs are appropriate for research and development of animal cells, tissues, and cell- and tissue-based products (ACTPs), gene therapies, and heritable intentional genomic alterations (IGAs) in animals.

DATES: Submit either electronic or written comments on the draft guidance by March 10, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–5376 for ''Type VII Veterinary Master File for Research and Development and Risk Reviews.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lynne Boxer, Center for Veterinary Medicine, Food and Drug

Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0611, *lynne.boxer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #260 entitled ''Type VII Veterinary Master File for Research and Development and Risk Reviews.'' A Type VII VMF is a file that can receive submissions to FDA's Center for Veterinary Medicine (CVM) that may contain confidential data and information related to unique regulatory considerations such as research and development of an ACTP, an IGA in an animal, gene therapy, or a risk review for an ACTP or IGA in an animal, where the information submitted is generally not intended to support product approval. The benefits of a Type VII VMF include: (1) confidential exchange of information with FDA that is not subject to user fees, (2) an opportunity for increased communication with FDA during early stages of product development, and (3) a process for reporting research studies outside of an investigational file.

The scope of this draft guidance is limited to the use of Type VII VMFs for research and development and risk review requests. There are other uses of Type VII VMFs, but they are not addressed in this draft guidance.

The use of a Type VII VMF is appropriate for research and development of ACTPs, gene therapies, and IGAs in animals, and for risk review of ACTPs and IGAs in animals because, for these types of novel products and rapidly evolving technologies, there may be unique regulatory considerations, concerning different types of issues, that may call for a developer's interactions with CVM at an earlier stage than would normally take place with traditional products that CVM regulates. As described in the draft guidance, developers should open a Type VII VMF to cover these interactions with CVM.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on Type VII Veterinary Master File for Research and Development and Risk Reviews. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31531 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–4778]

Heritable Intentional Genomic Alterations in Animals of Food-Producing Species for Use as Models of Disease; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry (GFI) #251 entitled ''Heritable Intentional Genomic Alterations in Animals of Food-Producing Species for Use as Models of Disease.'' This draft guidance, when finalized, will set forth FDA's policy regarding heritable intentional genomic alterations (IGAs) in animals of food-producing species, such as swine and rabbits, that are intended to be marketed for use as models of human or animal disease in biomedical research under contained and controlled conditions. The draft guidance describes the conditions under which we generally may not expect developers of IGAs in animal models of disease to submit an application to FDA's Center for Veterinary Medicine (CVM) or to get our approval before marketing their animals following CVM's prior review of risk factor data.

DATES: Submit either electronic or written comments on the draft guidance by March 10, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–4778 for ''Heritable Intentional Genomic Alterations in Animals of Food-Producing Species for Use as Models of Disease.'' Received comments will be placed in the docket and, except

for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Adam Moyer, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–796–2319, *Adam.Moyer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #251 entitled ''Heritable Intentional Genomic Alterations in Animals of Food-Producing Species for Use as Models of Disease.'' This guidance, when finalized, will set forth FDA's policy regarding IGAs in animals of food-producing species, such as swine and rabbits, that are intended to be marketed for use as models of human or animal disease in biomedical research under contained and controlled conditions (IGAs in animal models of disease). This research may be basic research of general applicability (*e.g.,* understanding the underlying pathophysiology of a disease or disease processes) or it may be research or pre-clinical testing for a particular medical product that may support an application for product approval (*e.g.,* preclinical trials of safety or effectiveness in altered animal models closely resembling human disease).

In the **Federal Register** of May 2, 2024 (89 FR 35834), we announced the availability of final GFI #187A entitled ''Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach.'' GFI #187A clarifies that heritable IGAs in animals are subject to FDA oversight and are regulated according to our risk-based regulatory approach. GFI #187A indicates that while, in general, FDA approval of IGAs in animals is required, under certain conditions we do not expect developers of IGAs in animals to submit an application or get our approval before marketing their product following our prior review of risk factor data. Among these IGAs are those that GFI #187A describes as Category 2, for which we may not expect developers to submit an application for approval if, after analyzing data submitted about a product's risks, we find we understand the product's risks for the specified intended use; any identified risks, including their potential severity and likelihood of occurring, are appropriately mitigated; and we have no further questions for which we would need to see additional data.

In this draft GFI #251, we address those circumstances under which we may not expect developers to submit an application for approval of an IGA in an animal model of disease if, after looking at data submitted about that product's risk, we determine that it appropriately fits in Category 2. FDA believes that IGAs in animal models of disease are likely to fit in Category 2 in part because the animals are unlikely to enter the food supply or to escape and establish themselves in the environment. For these reasons, based on case-by-case evaluation of data and information as described in draft GFI #251, we may determine that IGAs in an animal model of disease fits in Category 2, and we do not expect developers of these IGAs to submit an application for approval to us prior to marketing.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Heritable Intentional Genomic Alterations in Animals of Food-Producing Species for Use as Models of Disease.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032; the collections of information in 21 CFR part 511 have been approved under OMB control number 0910–0117; and the collections of information in 21 CFR part 58 have been approved under OMB control number 0910–0119.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31530 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0053]

Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers; Guidance for Industry; Availability; Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request

AGENCY: Food and Drug Administration, HHS

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers.'' This guidance describes FDA's enforcement policy regarding certain firm-initiated communications of scientific information on unapproved use(s) of the firm's approved/cleared medical products to health care providers (HCPs) engaged in prescribing or administering medical products to individual patients. This guidance finalizes the revised draft guidance of the same title issued in October 2023. The October 2023 revised draft guidance revised and replaced the draft guidance entitled ''Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices,'' issued in March 2014, which itself revised the final guidance entitled ''Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices,'' issued in January 2009. This guidance is not for current implementation, pending the Office of Management and Budget's (OMB's) decision on the collection of information.

DATES: The announcement of the guidance is published in the **Federal Register** on January 7, 2025. Submit written comments on the collection of information by February 21, 2025.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find the particular information collections by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control numbers that FDA is seeking to revise are 0910–0686 and 0910–0485. Also include the FDA docket number found in brackets in the heading of this document. You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2008–D–0053 for ''Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; the Office of Policy, Center for Devices

and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or the Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Kathleen David, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Room 3203, Silver Spring, MD 20993–0002, 301–796–1200; James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; Stephanie Philbin, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993–0002, 301–837–7151; Kathryn Dennehy, Office of Surveillance and Compliance, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–7002; or Julie Finegan, Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4252, Silver Spring, MD 20993–0002, 301–827–4830.

Regarding the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers.'' This guidance describes FDA's enforcement policy regarding certain firm-initiated communications of scientific information on unapproved use(s) of the firm's approved/cleared medical products to HCPs engaged in prescribing or administering medical products to individual patients. FDA is issuing this guidance to provide reassurance to firms that, if they choose to provide communications consistent with the recommendations in this guidance, FDA does not intend to use the firm's dissemination of such communication standing alone as evidence of a new intended use. Additionally, FDA does not expect a firm to submit such a communication to the Agency at the time the communication is initially shared with HCPs. We acknowledge that firms communicate in other ways and with other audiences, and this guidance neither speaks to nor intends to convey any views on communications that are not within the scope of the enforcement policy outlined in this guidance.

The fact that a communication by a firm does not share all the characteristics of communications that are within the scope of this enforcement policy does not alone mean that FDA intends to rely on it to establish a new intended use. A key tenet underlying this enforcement approach is that, to promote the public health, any individual firm-initiated communication of scientific information about unapproved use(s) of that firm's approved/cleared medical product(s) should be truthful and non-misleading, and provide and appropriately present all information necessary for HCPs to understand and evaluate the strengths and weaknesses, validity, and clinical utility of the scientific information on unapproved use(s) in that specific communication. Accordingly, the guidance provides recommendations consistent with those principles. The guidance also describes the characteristics of the specific source publications contained in firm-initiated communications that fall within the enforcement policy outlined in this guidance.

Specifically, this guidance provides recommendations for firms initiating the sharing with HCPs of:

- Source publications that are:

—Published scientific or medical journal articles (reprints)

—Published clinical reference resources, as follows:

  - Clinical practice guidelines (CPGs)
  - Scientific or medical reference texts (reference texts)
  - Materials from digital clinical practice resources

- Firm-generated presentations of scientific information on unapproved use(s) provided with a source publication

For the purposes of this guidance, these specific types of firm-initiated communications to HCPs, in combination with the disclosures recommended in this guidance, are referred to as scientific information on unapproved use(s) of approved/cleared medical product communications (hereafter referred to as ''SIUU communications'').

This guidance finalizes the revised draft guidance of the same title issued in October 2023 (88 FR 73031). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include (1) reorganizing the guidance to include dedicated glossary and policy sections; (2) revising the recommendations for source publications to provide additional specificity and examples to illustrate the recommendations; (3) refining language around presentational considerations to provide additional clarity and an additional example; and (4) updating the section on firm-generated presentations to specify that the recommendations apply to firm-generated presentations of scientific information from any of the source publications addressed in the guidance. In addition, editorial changes were made for clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information for OMB review and clearance. This guidance is not for current implementation, pending OMB's decision on the collection of information.

Manufacturer Communications on Approved and Unapproved Uses of Drugs OMB Control Number 0910–0686—Revision; and Medical Device Labeling

OMB Control No. 0910–0485—Revision

The guidance document entitled ''Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers'' discusses third-party disclosure recommendations regarding information that we recommend firms include in SIUU

communications if the firms choose to publicly share such communications.

In the **Federal Register** of October 24, 2023 (88 FR 73031), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received in response to the four information collection topics solicited in the notice.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN—OMB CONTROL NO. 0910–0686 [1]

Information collection activity; guidance section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
A statement that the unapproved use(s) of the medical product has not been approved by FDA and that the safety and effectiveness of the medical product for the unapproved use(s) has not been established; section V. Q2.	747	30	22,410	0.1 (6 minutes)	2,241
A statement disclosing the FDA-approved use(s) of the medical product, including any limitations of use specified in the FDA-required labeling; section V. Q2.	747	27	20,169	0.1 (6 minutes)	2,016.9
A statement disclosing any limitations, restrictions, cautions, warnings, or precautions described in the FDA-required labeling about the unapproved use(s); section V. Q2.	747	5	3,735	0.2 (12 minutes) ...	747
A copy of the most current FDA-required labeling (or a mechanism for obtaining this labeling, as appropriate); section V. Q2.	747	27	20,169	0.1 (6 minutes)	2,016.9
A statement describing any contraindication(s) in the FDA-required labeling for the medical product; section V. Q2.	747	3	2,241	0.1 (6 minutes)	224.1
A statement describing any serious, life-threatening, or fatal risks posed by the medical product that are in the FDA-required labeling for the medical product or known by the firm and that are relevant to the unapproved use(s). If a risk evaluation and mitigation strategy (REMS) has been established under 21 U.S.C. 355–1, the statement should disclose that fact and should describe the goal(s) of the REMS; section V. Q2.	747	25	18,675	0.2 (12 minutes) ...	3,735
A statement identifying any authors, editors, or other contributors to publication(s) included in the SIUU communication who were employees of or consultants to or who received compensation from the firm at the time of writing, editing, or contributing to the publication, to the extent a firm acting reasonably would know of such relationship; section V. Q2.	747	20	14,940	0.2 (12 minutes) ...	2,988
In the case of an SIUU communication that includes one or more source publications primarily focused on a particular scientific study or studies, for each such study where the following information is not included in the source publication, provide a description of:. —All material aspects of study design, methodology, and results; —All material limitations related to the study design, methodology, and results; —Any conclusions—from other scientifically sound studies that evaluated the same or similar hypotheses or research questions—that are in conflict with the conclusions from the studies or analyses described in the source publication(s). The citations for any such studies should also be included; section V. Q2.	747	20	14,940	2.75	41,085
The publication date of any referenced or included source publication (if not specified in the source publication or citation); section V. Q2.	747	3	2,241	0.1 (6 minutes)	224.1
When a firm shares an SIUU communication that does not include a firm-generated presentation, but does include an unabridged CPG or reference text in its entirety that discusses a wide range of medical products and that discussion is not primarily focused on one or more of a firm's medical products, the firm should include, in lieu of some of the specific disclosures listed above, a more general statement in the SIUU communication, such as ''This [CPG/reference text] describes some uses of medical products that are not approved by FDA, and the safety and effectiveness of any unapproved use(s) have not been established.''; section V. Q4.	747	3	2,241	0.1 (6 minutes)	224.1
When a firm shares an SIUU communication that includes a firm-generated presentation of scientific information on unapproved use(s) provided with a source publication, that SIUU communication should clearly disclose what portions of the SIUU communication are firm-generated; section V. Q5.	747	10	7,470	0.1 (6 minutes)	747
Total	.....	.....	129,231	.....	56,249.1

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a current listing of firms promoting human and animal drug products in calendar year (CY) 2022, we assume 747 firms (''number of respondents'' in table 1) may each choose to publicly share 30 SIUU communications annually. Our estimate of the burden per disclosure (2.5 hours) reflects what we believe is the average burden based on the number and content and complexity of disclosures as recommended in the guidance.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN—OMB CONTROL NO. 0910–0485 [1]

Information collection activity; guidance section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
A statement that the unapproved use(s) of the medical product has not been approved by FDA and that the safety and effectiveness of the medical product for the unapproved use(s) has not been established; section V. Q2.	261	30	7,830	0.1 (6 minutes)	783
A statement disclosing the FDA-approved use(s) of the medical product, including any limitations of use specified in the FDA-required labeling; section V. Q2.	261	27	7,047	0.1 (6 minutes)	704.7
A statement disclosing any limitations, restrictions, cautions, warnings, or precautions described in the FDA-required labeling about the unapproved use(s); section V. Q2.	261	5	1,305	0.2 (12 minutes) ...	261
A copy of the most current FDA-required labeling (or a mechanism for obtaining this labeling, as appropriate); section V. Q2.	261	27	7,047	0.1 (6 minutes)	704.7
A statement describing any contraindication(s) in the FDA-required labeling for the medical product; section V. Q2.	261	3	783	0.1 (6 minutes)	78.3
A statement describing any serious, life-threatening, or fatal risks posed by the medical product that are in the FDA-required labeling for the medical product or known by the firm and that are relevant to the unapproved use(s). If a risk evaluation and mitigation strategy (REMS) has been established under 21 U.S.C. 355–1, the statement should disclose that fact and should describe the goal(s) of the REMS; section V. Q2.	261	25	6,525	0.2 (12 minutes) ...	1,305
A statement identifying any authors, editors, or other contributors to publication(s) included in the SIUU communication who were employees of or consultants to or who received compensation from the firm at the time of writing, editing, or contributing to the publication, to the extent a firm acting reasonably would know of such relationship; section V. Q2.	261	20	5,220	0.2 (12 minutes) ...	1,044
In the case of an SIUU communication that includes one or more source publications primarily focused on a particular scientific study or studies, for each such study where the following information is not included in the source publication, provide a description of:. —All material aspects of study design, methodology, and results —All material limitations related to the study design, methodology, and results —Any conclusions—from other scientifically sound studies that evaluated the same or similar hypotheses or research questions—that are in conflict with the conclusions from the studies or analyses described in the source publication(s). The citations for any such studies should also be included; section V. Q2	261	20	5,220	2.75	14,355
The publication date of any referenced or included source publication (if not specified in the source publication or citation); section V. Q2.	261	3	783	0.1 (6 minutes)	78.3
When a firm shares an SIUU communication that does not include a firm-generated presentation, but does include an unabridged CPG or reference text in its entirety that discusses a wide range of medical products and that discussion is not primarily focused on one or more of a firm's medical products, the firm should include, in lieu of some of the specific disclosures listed above, a more general statement in the SIUU communication, such as ''This [CPG/reference text] describes some uses of medical products that are not approved by FDA and the safety and effectiveness of any unapproved use(s) have not been established.''; section V. Q4.	261	3	783	0.1 (6 minutes)	78.3
When a firm shares an SIUU communication that includes a firm-generated presentation of scientific information on unapproved use(s) provided with a source publication, that SIUU communication should clearly disclose what portions of the SIUU communication are firm-generated; section V. Q5.	261	10	2,610	0.1 (6 minutes)	261
Total	.....	.....	45,153	.....	19,653.3

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on an estimated number of device firms marketing products in calendar year (CY) 2022, we assume 261 firms (''number of respondents'' in table 1) may each choose to publicly share 30 SIUU communications annually. Our estimate of the burden per disclosure (2.5 hours) reflects what we believe is the average burden based on the number and content and complexity of disclosures as recommended in the guidance.

FDA is issuing this final guidance subject to OMB approval of the collection of information. Before implementing the guidance, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the collection of information.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm, https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31539 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4976]

Pulse Oximeters for Medical Purposes—Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Pulse Oximeters for Medical Purposes—Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations.'' This draft guidance document, when finalized, will provide recommendations regarding non-clinical and clinical performance testing of certain pulse oximeters for medical purposes, including devices with a pulse oximeter function that estimates the amount of oxygen in arterial blood and pulse rate. These recommendations are being proposed based in part on concerns that the accuracy of pulse oximeters can be affected by, among other factors, a person's skin pigmentation. The recommendations are being proposed to inform the performance evaluation for these devices, to support premarket submissions, regardless of submission type, and to promote consistency and facilitate efficient review of these submissions. Among other topics, the draft guidance also proposes recommendations for labeling, which are intended to promote the safe and effective use of pulse oximeters and help users understand the benefits and risks associated with the use of the device. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by March 10, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–4976 for ''Pulse Oximeters for Medical Purposes—Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Pulse Oximeters for Medical Purposes—Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Kumudhini Hendrix, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire

Ave., Bldg. 66, Rm. 1259, Silver Spring, MD 20993–0002, 240–402–5262.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document proposes recommendations regarding non-clinical and clinical performance testing of certain pulse oximeters for medical purposes, including devices with a pulse oximeter function that estimates the amount of oxygen in arterial blood and pulse rate. Pulse oximeters are widely used by many types of healthcare providers and lay-users to obtain an indirect measure of arterial blood oxygen saturation. These recommendations are being proposed based in part on concerns that the accuracy of pulse oximeters can be affected by, among other factors, a person's skin pigmentation. The recommendations are being proposed to inform the performance evaluation for these devices, to support premarket submissions, regardless of submission type, and to promote consistency and facilitate efficient review of these submissions. Among other topics, the draft guidance also proposes recommendations for labeling that are intended to promote the safe and effective use of pulse oximeters and help users understand the benefits and risks associated with the use of the device.

In recent years, FDA has engaged interested parties regarding how the Agency can help to ensure patients have access to high-quality, safe, and effective pulse oximeters intended for medical purposes. Current scientific evidence from laboratory desaturation studies suggests that there are accuracy differences in some pulse oximeters, especially in lower arterial blood oxygen saturations, between lightly and darkly pigmented individuals. On November 1, 2022, FDA convened the Anesthesiology and Respiratory Therapy Devices Panel (2022 Panel) of the Medical Devices Advisory Committee. The 2022 Panel indicated that clinical evidence for prescription pulse oximeters showed disparate performance in patients with dark skin pigmentation (as compared to patients with light skin pigmentation), which causes increased risk for the patient for their given disease outcome. The 2022 Panel also indicated that factors other than skin pigmentation, including but not limited to low perfusion, explain some of the disparate performance. The 2022 Panel recommended standardization of skin pigmentation assessment and that overall, pulse oximeters for clinical use should be more accurate. In a discussion paper issued on November 16, 2023, FDA requested public comment on a series of questions related to an approach to improve the quality of premarket studies and associated methods used to evaluate the performance of pulse oximeters (Docket No. FDA–2023–N–4976), taking into consideration a participant's skin pigmentation and participant-reported race and ethnicity. On February 2, 2024, FDA reconvened the Panel (''2024 Panel'') to discuss a proposed approach for these issues. The 2024 Panel was also asked to discuss the type and amount of data that should be provided by manufacturers to FDA to evaluate the performance of pulse oximeters submitted for premarket review, including prescription and over-the-counter indications, and labeling considerations. After discussing the advantages and challenges, the 2024 Panel was in general agreement with the proposed approach. FDA considered comments from the discussion paper and Panel meetings and incorporated the feedback as appropriate in developing this draft guidance. FDA strongly encourages interested persons to submit comments regarding this topic, including any clinical studies or information that may be relevant for consideration.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Pulse Oximeters for Medical Purposes—Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* and at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Pulse Oximeters for Medical Purposes—Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00001605 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
812	Investigational Device Exemption.	0910–0078
860, subpart D	De Novo classification process.	0910–0844
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification.	0910–0485

21 CFR part or guidance	Topic	OMB control No.
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
50, 56	Protection of Human Subjects and Institutional Review Boards.	0910–0130

Dated: December 26, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31540 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0053]

Notifying the Food and Drug Administration of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act.'' This guidance updates the previous version of the guidance, of the same title, issued on November 17, 2023, and finalizes the concurrently issued draft guidance entitled ''Select Updates for the 506J Guidance: 506J Device List and Additional Notifications.'' This guidance finalizes a list of device product codes for which a manufacturer of such devices is required to notify FDA in accordance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) (hereafter referred to as the ''506J Device List'') and clarifies that manufacturers may submit voluntary notifications regarding supply chain issues at any time, unrelated to the declaration or potential declaration of a public health emergency (PHE).

DATES: The announcement of the guidance is published in the **Federal Register** on January 7, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–0053 for ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Tammy Beckham, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5500, Silver Spring, MD 20993–0002, 301–796–9081 or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 506J of the FD&C Act (21 U.S.C. 356j) provides FDA with authorities intended to help prevent or mitigate device shortages ''during, or in advance of, a public health emergency'' declared under section 319 of the Public Health Service Act (PHS Act) (42 U.S.C. 247d). On December 29, 2022, the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act was signed into law as part of the Consolidated Appropriations Act, 2023, Public Law 117–328 (hereafter referred to as the FY 2023 Omnibus). Section 2514(c) of the FY 2023 Omnibus directed FDA to issue or revise guidance regarding requirements under section 506J of the FD&C Act and include a list of each device product code for which a manufacturer of such device is required to notify FDA in accordance with section 506J. Section 2514 of the FY 2023 Omnibus amended section 506J of the FD&C Act to add section 506J(h), ''Additional Notifications'' and directed FDA to issue guidance ''to facilitate voluntary notifications.''

This final guidance includes the 506J Device List. The 506J Device List is based on the requirements under section 506J(a) of the FD&C Act. In section 2514 of the FY 2023 Omnibus, Congress directed FDA to issue guidance on the requirements under section 506J of the FD&C Act and to include ''a list of each device product code for which a manufacturer of such device is required to notify the Secretary in accordance with section 506J.'' Thus, manufacturers of a device on the 506J Device List must notify FDA in accordance with section 506J of the FD&C Act for each such device. For more information, manufacturers should see the 506J Device List web page, available at *https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/506j-device-list*. FDA expects that the list will evolve over time and FDA intends to periodically reevaluate the list.

Additionally, consistent with section 506J(h) of the FD&C Act, FDA has clarified that manufacturers may submit, and FDA may receive, voluntary notifications regarding supply chain issues at any time, unrelated to the declaration or potential declaration of a PHE.

This guidance updates the final guidance ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act.'' This guidance also finalizes the concurrently issued draft guidance entitled ''Select Updates for the 506J Guidance: 506J Device List and Additional Notifications.'' A notice of availability for these guidances appeared in the **Federal Register** of November 17, 2023 (88 FR 80310). Additionally, FDA received recommendations from the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee on February 6, 2024. FDA considered comments received and revised the draft guidance as appropriate in response to the comments, including updating the 506J Device List and providing additional clarity regarding the development of the 506J Device List. The guidance also includes additional information regarding potential updates to the 506J Device List and how to contact FDA regarding devices on the 506J Device List.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00021003 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

Guidance	Topic	OMB control No.
''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act''.	Shortages Data Collection ...	0910–0491

Dated: December 26, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31547 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–4488]

Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Artificial Intelligence Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations.'' This draft guidance, when finalized, will provide recommendations regarding the contents of marketing submissions for devices that include artificial intelligence (AI)-enabled device software functions including documentation and information that will support FDA's evaluation of safety and effectiveness. To support the development of appropriate documentation for FDA's assessment of the device, this draft guidance also proposes recommendations for the design, development, and implementation of AI-enabled devices that sponsors may wish to consider using throughout the total product lifecycle (TPLC). This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by April 7, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–4488 for ''Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Sonja Fulmer, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5536, Silver Spring, MD 20993–0002, 240–402–5979; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911; or Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire

Ave., Hillandale Bldg., 4th Floor, Silver Spring, MD 20993–0002, 301–796–3400.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has long promoted a TPLC approach to oversight of medical devices, including AI-enabled devices, and has committed to developing guidances and resources for such an approach. Some recent efforts include developing guiding principles for good machine learning practice (GMLP) and transparency for machine learning-enabled devices to help promote safe, effective, and high-quality machine learning models; and a public workshop on fostering a patient-centered approach to AI-enabled devices, including discussion of device transparency for users. This draft guidance intends to continue these efforts, by proposing recommendations tailored to a TPLC approach for AI-enabled devices. This draft guidance, when finalized, will provide recommendations regarding the contents of marketing submissions for devices that include AI-enabled device software functions including documentation and information that will support FDA's evaluation of safety and effectiveness. The recommendations reflect a comprehensive approach to the management of risk throughout the device TPLC. To support the development of appropriate documentation for FDA's assessment of the device, this draft guidance also proposes recommendations for the design, development, and implementation of AI-enabled devices that manufacturers may wish to consider using throughout the TPLC. This draft guidance, when finalized, also will include FDA's current thinking on strategies to address transparency and bias throughout the TPLC of AI-enabled devices, including by collecting evidence to evaluate whether a device benefits all relevant demographic groups (*e.g.,* race, ethnicity, sex, and age) similarly, to help ensure that these devices remain safe and effective for their intended use. These interconnected considerations are important throughout the TPLC and should be incorporated from the earliest stages of device development through decommission to help design transparency into the device. Finally, this draft guidance proposes recommendations that address the performance of AI-enabled devices in the postmarket setting.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Artificial Intelligence Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Other Considerations

The recommendations discussed within the document are based upon FDA's experience with reviewing a diversity of AI-enabled devices and current regulatory science research. However, FDA understands that the development of AI is an evolving field, with experts from many different sectors that can contribute to the development of AI-enabled devices. FDA requests public comment from all interested stakeholders on the following items:

- How well the proposed recommendations align with the AI lifecycle.
- The adequacy of the recommended documentation to be included in a marketing submission to address concerns that may be raised with AI-enabled devices that use emerging technology, such as generative AI.
- The proposed approach to performance monitoring, including use of a performance monitoring plan as a means of risk mitigation for AI-enabled devices.
- The proposed approach to the type of information that should be conveyed to users about AI-enabled devices, including the example model card.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Artificial Intelligence Enabled Device Software Functions: Lifecycle Management and Premarket Submission Recommendations'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00007028 and complete title to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Use Devices; Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification.	0910–0485

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31543 Filed 1–6–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2648]

Heritable Intentional Genomic Alterations in Animals: The Approval Process; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry #187B entitled ''Heritable Intentional Genomic Alterations in Animals: The Approval Process.'' This guidance clarifies FDA's requirements and recommendations for developers of intentional genomic alterations (IGAs) in animals. The guidance is one of two companion documents. ''Heritable Intentional Genomic Alterations in Animals: The Approval Process'' describes how the FDA approval process applies to heritable IGAs in animals. The companion final guidance, GFI #187A entitled ''Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach,'' describes FDA's risk-based regulatory approach to the oversight of heritable IGAs in animals.

DATES: The announcement of the guidance is published in the **Federal Register** on January 7, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–2648 for ''Heritable Intentional Genomic Alterations in Animals: The Approval Process.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Adam Moyer, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–796–2319, *Adam.Moyer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On May 2, 2024, FDA announced in the **Federal Register** the availability of two companion guidances to describe FDA's approach to regulating IGAs in animals. The notice of availability of the first of these two guidances, final GFI #187A, entitled ''Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach'' (89 FR 35832), describes FDA's risk-based approach to the oversight of IGAs in animals.

The second companion IGA guidance, draft GFI #187B entitled ''Heritable Intentional Genomic Alterations in Animals: The Approval Process'' (89 FR 35834), describes how the FDA approval process applies to heritable IGAs in animals. Interested parties had until July 31, 2024, to comment on the draft guidance.

FDA received approximately 5,000 comments on draft GFI #187B, with 4,982 of them resulting from two write-in campaigns. Those campaigns

criticized FDA regulation of IGAs in animals for neglecting animal welfare. The remaining comments came from industry (companies that produce IGAs and trade associations), individual developers of IGAs in animals, academics, non-governmental organizations (consumer, environmental), and individual consumers.

FDA has made changes in the final GFI #187B that include additional explanation or clarification about: (1) how FDA's animal safety review includes animal health and well-being; (2) how compositional analysis relates to the food safety evaluation; (3) what FDA means by a ''significant change'' with respect to durability; (4) what can be included in a single IGA-related application; (5) what methods, including methods other than whole genome sequencing, may be most appropriate for molecular characterization of the lineage of animals with the IGA; (6) further clarification regarding data expectations, including what data constitutes a ''full characterization'' of the site of alteration and potential unintended alterations; and (7) more detailed information on review timelines. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated May 2024.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Heritable Intentional Genomic Alterations in Animals: The Approval Process.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 25 have been approved under OMB control number 0910–0322; the collections of information in 21 CFR part 58 have been approved under OMB control number 0910–0119; the collections of information in 21 CFR part 207 have been approved under OMB control number 0910–0045; the collections of information in 21 CFR part 211 have been approved under OMB control number 0910–0139; the collections of information in 21 CFR part 511 have been approved under OMB control number 0910–0117; the collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0284; and the collections of information in 21 CFR 558.6(a)(4) have been approved under OMB control number 0910–0363.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31532 Filed 1–6–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–4689]

Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products; Draft Guidance for Industry; Availability; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products.'' In accordance with its mission of protecting, promoting, and advancing public health, FDA's Center for Drug Evaluation and Research (CDER), in collaboration with the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), the Center for Veterinary Medicine (CVM), the Oncology Center of Excellence (OCE), the Office of Combination Products (OCP), and the Office of Inspections and Investigations (OII), is issuing this draft guidance to provide recommendations to industry on the use of artificial intelligence (AI) to produce information or data intended to support regulatory decision-making regarding the safety, effectiveness, or quality for drug and biological products.

DATES: Submit either electronic or written comments on the draft guidance by April 7, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by April 7, 2025.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No.

FDA–2024–D–4689 for ''Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products; Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Tala Fakhouri, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6330, Silver Spring, MD 20993–0002, 301–837–7407, *Tala.Fakhouri@fda.hhs.gov;* James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911, *James.Myers@fda.hhs.gov;* or Sonja Fulmer, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5530, Silver Spring, MD 20993–0002, 240–402–5979, *Sonja.Fulmer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products.'' This draft guidance, when finalized, will provide recommendations to industry on the use of AI to produce information or data intended to support regulatory decision-making regarding safety, effectiveness, or quality for drugs. Specifically, this guidance proposes a risk-based credibility assessment framework that may be used for establishing and evaluating the credibility of an AI model for a particular context of use (COU). For the purposes of this guidance, credibility refers to trust, established through the collection of credibility evidence, in the performance of an AI model for a particular COU. Credibility evidence is any evidence that could support the credibility of an AI model output for a specific COU. The COU defines the specific role and scope of the AI model used to address a question of interest. This guidance does not endorse the use of any specific AI approach or technique.

This draft guidance discusses the use of AI models in the nonclinical, clinical, postmarketing, and manufacturing phases of the drug product life cycle, where the specific use of the AI model is to produce information or data to support regulatory decision-making regarding safety, effectiveness, or quality for drugs. This draft guidance does not address the use of AI models: (1) in drug discovery or (2) when used for operational efficiencies (*e.g.,* internal workflows, resource allocation, drafting/writing a regulatory submission) that do *not* impact patient safety, drug quality, or the reliability of results from a nonclinical or clinical study. We encourage sponsors to engage with FDA early if they are uncertain about whether or not their use of AI is within the scope of this guidance.

The Agency recognizes that the use of AI in drug development is broad and rapidly evolving. This draft guidance, when finalized, is expected to help ensure that AI models used to support regulatory decision-making are sufficiently credible for the COU. The risk-based credibility assessment framework proposed in this draft guidance is intended to help sponsors and other interested parties plan, gather, organize, and document information to establish the credibility of AI model outputs. As described in this guidance, the proposed recommendations, considerations, and assessment activities (*e.g.,* the level of oversight, the stringency of the credibility assessments and the performance acceptance criteria, the risk mitigation strategy, and the amount of documentation and detail associated with AI use) that can be used to establish model credibility will generally be tailored to the specific COU and will depend on model risk.

This draft guidance also describes different options by which industry may engage with the Agency on issues related to AI model development. The draft guidance emphasizes the importance of early engagement with the Agency to help: (1) set expectations regarding the appropriate credibility assessment activities for the proposed model based on model risk and COU and (2) identify potential challenges and how such challenges may be addressed. The Agency recognizes, however, that certain uses of AI occur outside of the product development and marketing application processes with established meeting options. Specifically, in the context of postmarketing pharmacovigilance, certain documentation (*e.g.,* processes and procedures) is not generally submitted to the Agency but is maintained according to the sponsor's standard operating procedures and made available to the Agency upon request (*e.g.,* during an inspection). In such cases, sponsors may choose to complete all the steps outlined in the draft guidance without seeking early engagement with the Agency. Sponsors remain responsible for compliance with statutory and regulatory requirements,

including postmarketing safety surveillance and reporting requirements, regardless of the technology utilized.

The Agency also recognizes that sponsors may have questions about credibility assessment plans in connection with the postmarketing phase. Therefore, the Agency seeks feedback about whether development of additional guidance specific to the use of AI models in postmarketing pharmacovigilance would be helpful and, if so, the topics that would be most useful for the Agency to address. For general discussion about the use of AI models or other emerging technologies in pharmacovigilance, FDA has established the Emerging Drug Safety Technology Meeting (EDSTM) Program.

The risk-based credibility assessment framework proposed within the draft guidance is informed by: (1) over 800 comments received on the 2023 discussion papers published by CDER entitled ''Using Artificial Intelligence & Machine Learning in the Development of Drug & Biological Products'' (*https://www.fda.gov/media/167973/download*) and ''Artificial Intelligence in Drug Manufacturing'' (*https://www.fda.gov/media/165743/download*); (2) FDA's experience with reviewing over 300 submissions with AI and machine learning components across all phases of the drug development process; and (3) current regulatory science research. However, FDA understands that this is a rapidly evolving field, involving multidisciplinary expertise. FDA requests public comment from industry and all other interested parties on the guidance, with emphasis on the following items:

- How well the proposed risk-based credibility assessment framework aligns with industry's experience; and
- Whether the options available for sponsors and other interested parties to engage with FDA on AI are sufficient.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the use of AI to support regulatory decision-making for drug and biological products. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31542 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0756]

Validation and Verification of Analytical Testing Methods Used for Tobacco Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry entitled ''Validation and Verification of Analytical Testing Methods Used for Tobacco Products.'' The guidance provides information and recommendations related to the validation and verification of analytical test methods, including analytical testing of tobacco product constituents, ingredients, and additives, as well as stability testing of tobacco products. This guidance is intended to help industry produce more consistent and reliable analytical data used to support regulatory submissions for finished tobacco products. This guidance finalizes the draft guidance of the same title issued in December 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on January 7, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–D–0756 for ''Validation and Verification of Analytical Testing Methods Used for Tobacco Products.''

Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Robert Schwartz or Nathan Mease, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Validation and Verification of Analytical Testing Methods Used for Tobacco Products.'' This guidance provides information and recommendations on how tobacco product manufacturers can produce validation and verification data for the analytical procedures and methods used to support regulatory submissions for finished tobacco products including substantial equivalence (SE) reports, premarket tobacco product applications (PMTA), and modified risk tobacco product applications (MRTPA). Additionally, the principles in this guidance may be used for finished tobacco product testing and reporting of harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires, among other things, premarket review for new tobacco products and modified risk tobacco products (see sections 910 and 911 of the FD&C Act (21 U.S.C. 387j and 21 U.S.C. 387k)) and reporting of harmful and potentially harmful constituents under section 904 of the FD&C Act (21 U.S.C. 387d). Regulatory submissions often contain data from analytical testing, such as data about ingredients, constituents, and additives. In standard practice, analytical testing is done through validation of the analytical test method. In these cases, the applicant will want to use analytical test methods that are sufficiently precise, accurate, selective, and sensitive. Validation involves documenting, using specific laboratory investigations, that the performance characteristics of the test method are suitable and reliable for the intended analytical applications, in terms of precision, accuracy, selectivity, and sensitivity. This guidance is intended to help industry produce more consistent and reliable analytical data used to support regulatory submissions for finished tobacco products, such as SE, PMTA, MRTPA submissions, and for finished tobacco product testing and reporting of HPHCs in tobacco products and tobacco smoke.

This guidance finalizes the draft guidance of the same title issued on December 22, 2021 (86 FR 72603). FDA considered comments received on the draft guidance and revised the final guidance as appropriate in response to the comments. Changes from the draft to the final guidance include:

• Updates to the Background section reflecting statutory revisions to the term ''tobacco product'' to include non-tobacco (synthetic) nicotine (see Pub. L. 117–103);

• Acknowledgment that alternative validation procedures and recommendations may differ from those in this guidance;

• Expression of the Agency's support for the use of national and international standard analytical test methods for the analysis of finished tobacco products;

• The addition of definitions for several new terms and revisions to several existing definitions to improve clarity;

• Updates reflecting PMTA rule and SE Report rule requirements for documenting laboratory accreditation;

• Updates to citations supporting the replicate recommendations in the guidance and for alternative validation procedures;

• Corrections, revisions, or clarifications to calculations, formulas or equations, or units of measure in the text and tables;

• The addition of an equation as an approach to adjust for interference bias when determining selectivity;

• Clarification of the Agency's thinking on the adequacy of linear regression (R^2) for determining the linearity parameter as part of analytical test method validation;

• The addition of a spike and recovery approach for determining the limit of detection in order to provide flexibility in the analytical sampling procedure recommendations;

• Expansion on the discussion of tobacco product reference standards; and

• Editorial revisions to the text to improve clarity and consistency of terms used throughout the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Validation and Verification of Analytical Testing Methods Used for Tobacco Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements

of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in section 910(c)(1)(A)(i) of the FD&C Act have been approved under OMB control number 0910–0768; the collections of information in section 905(j) of the FD&C Act (21 U.S.C. 387e(j)) have been approved under OMB control number 0910–0673; the collections of information in 21 CFR part 1107 have been approved under OMB control number 0910–0684; the collections of information in section 904(a)(3) of the FD&C Act have been approved under OMB control number 0910–0732, and the collections of information in 21 CFR part 1114 have been approved under OMB control number 0910–0879.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the guidance at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/tobacco-products/rules-regulations-and-guidance-related-tobacco-products/guidance-related-tobacco-products,* or *https://www.regulations.gov.*

Dated: December 26, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31541 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–5591]

Evaluation of Sex-Specific and Gender-Specific Data in Medical Device Clinical Studies; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Evaluation of Sex-Specific and Gender-Specific Data in Medical Device Clinical Studies.'' This document provides guidance on the study and evaluation of sex- and/or gender-specific data in clinical investigations or research involving one or more subjects to determine the safety or effectiveness of a device. The purpose of this guidance is to encourage science-driven consideration of sex and/or gender, as appropriate for both the scientific question being addressed and the intended use of the device, when designing medical device clinical studies and reporting data from such studies in accordance with legal requirements. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by April 7, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–D–5591 for ''Evaluation of Sex-Specific and Gender-Specific Data in Medical Device Clinical Studies.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Evaluation of Sex-Specific and Gender-Specific Data in Medical Device Clinical Studies'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Terri Cornelison, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5516, Silver Spring, MD 20993–0002, 301–796–5682; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Recognition of the importance of sex- and gender-specific considerations has been steadily growing in areas such as medical technology design and development, including clinical study design, and assessing product performance throughout the total product life cycle and other medical device-related matters. Sex and gender are key considerations in the development and performance of medical devices. Although there has been steady growth in the recognition of sex- and gender-considerations in medical technology design and development, it is important to understand that this was not always the case. Historically, females and/or women have been under-represented in or excluded from many clinical studies. This has led to a lack of information available for females and/or women and their health care providers regarding the benefits and risks of many medical devices. Further, individuals with intersex traits and those with differences in sex development may have not been properly included within clinical studies. In addition, historically, as gender was often conflated with sex or otherwise not properly reported in clinical studies, there is a lack of data regarding the underrepresentation of nonbinary, transgender, fluid gender identities and other gender identities.

Given these historical concerns and the growing recognition of the importance of sex- and gender-specific considerations in medical technology design and development, it is important that a medical device be developed and evaluated with study participants that represent the demographic, clinical, and disease characteristics of the intended population. The purpose of this draft guidance is to encourage science-driven consideration of sex and/or gender. Upon finalization, this document will update the policy reflected in the existing guidance entitled ''Evaluation of Sex-Specific Data in Medical Device Clinical Studies'' by addressing both sex- and gender-specific data and will replace the existing guidance. As such, the recommendations within the guidance have been updated to help sponsors consider sex- and/or gender-specific data, as appropriate for the scientific questions being addressed and the intended use of the device, when designing medical device clinical studies and reporting data from such studies in accordance with legal requirements. The guidance provides recommendations for sponsors to consider sex- and/or gender-specific data throughout the clinical study process. This includes updated recommendations for clinical study design, study participant enrollment, data collection and analysis, and reporting of study information for sex-specific data, gender-specific data, or both, according to the scientific question at hand.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Evaluation of Sex-Specific and Gender-Specific Data in Medical Device Clinical Studies.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Evaluation of Sex-Specific and Gender-Specific Data in Medical Device Clinical Studies'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00001727 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR Part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756
800, 801, and 809	Medical Device Labeling Regulations.	0910–0485
822	Postmarket Surveillance of Medical Devices.	0910–0449

21 CFR Part or guidance	Topic	OMB control No.
50, 56	Protection of Human Subjects and Institutional Review Boards.	0910–0130

Dated: December 26, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31526 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0553]

Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act; Guidance for FDA Staff and Interested Parties; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for FDA staff and interested parties entitled ''Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act.'' This guidance document provides our current thinking on the approach we generally intend to take when we evaluate the public health importance of a food allergen other than one of the major food allergens (*i.e.,* milk, eggs, fish, Crustacean shellfish, tree nuts, wheat, peanuts, soybean, and sesame) listed in the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: The announcement of the guidance is published in the **Federal Register** on January 7, 2025.

ADDRESSES: You may submit either electronic or written comments on FDA guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–N–0553 for ''Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Chemical Contaminants, Office of Post-Market Assessment, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Stefano Luccioli, Office of Post-Market Assessment, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1283; or Alexandra Beliveau, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for FDA staff and interested parties entitled ''Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of April 19, 2022 (87 FR 23181), we announced the availability of a draft guidance for FDA staff and stakeholders entitled ''Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act.'' We gave interested parties until August 17, 2022, to submit comments for us to consider before beginning work on the final version of the guidance.

This guidance finalizes the approach we generally intend to take when evaluating the public health importance of a non-listed food allergen. The guidance specifies the scientific factors and other information relevant to the labeling and production of food containing the food allergen that we generally intend to consider when evaluating the public health importance of a non-listed food allergen. It also describes our recommendations for how to identify and evaluate the body of evidence applicable to an evaluation of the public health importance of a non-listed food allergen.

Food allergy can be broadly defined as an adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food. A food allergen is the food or component(s) (often a protein) of a food that elicits specific immunologic reactions. While many different types of food allergies have been identified, food allergies that are most studied and understood clinically are those due to immunoglobulin E antibodies (IgE) that cause the body to release inflammatory chemicals. The most severe and immediately life-threatening food allergies are those that are mediated by IgE and are capable of triggering anaphylaxis, which can be fatal. The focus of this guidance is primarily IgE-mediated food allergy. However, we recognize that food allergens acting through other mechanisms may raise public health concerns. We intend to evaluate the public health importance of these allergens on a case-by-case basis. We will also continue gathering scientific data and other information on food allergens acting through other mechanisms to help inform possible future action on these allergens, which may include future guidance or communications to the public.

In general, the regulatory framework of the FD&C Act and our regulations implementing the FD&C Act broadly apply to the production of food that is or contains a food allergen through statutory and regulatory provisions regarding: (1) food labeling; (2) food production (*e.g.,* manufacturing, processing, packing, and holding food); and (3) the safety of substances added to food. Under section 403(w) of the FD&C Act (21 U.S.C. 343(w)), a food is misbranded if it contains a major food allergen and fails to declare that major food allergen as specified on its label using the major food allergen's common or usual name. Section 201(qq)(1) of the FD&C Act (21 U.S.C. 321(qq)(1)) defines a ''major food allergen,'' in part, as any of the following: milk, eggs, fish (*e.g.,* bass, flounder, or cod), Crustacean shellfish, tree nuts (*e.g.,* almonds, pecans, or walnuts), wheat, peanuts, soybeans, and sesame.

We considered all comments received during the comment period before developing the final guidance. Some comments on the draft guidance requested that we expand the scope of the guidance to cover non-IgE-mediated food allergies and to describe the potential regulatory options available to FDA. Other comments recommended that FDA define specific targets for each evaluation factor laid out in the framework. We have modified the final guidance where appropriate. Changes to the guidance include:

- Clarifying that evidence of non-IgE-mediated reactions can be useful as supplemental data in an evaluation of the public health importance of a food allergen;
- Incorporating updated text and a revised reference to reflect the recent publication of the Food and Agricultural Organization of the United Nations and World Health Organization's Expert Committee meeting report; and
- Expanding the discussion regarding prevalence data when a food is not regularly consumed in the United States.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 10 have been approved under OMB control number 0910–0191. The collections of information in 21 CFR part 101 have been approved under OMB control number 0910–0381. The collections of information in section 403(w) of the FD&C Act have been approved under OMB control number 0910–0792. The collections of information in 21 CFR part 117 have been approved under OMB control number 0910–0751. The collections of information for Form FDA 3800 have been approved under OMB control number 0910–0645. The collections of information for Form FDA 3500 have been approved under OMB control number 0910–0291. The collections of information in 21 CFR 70.25, 71.1, 170.36, 171.1, 172, 173, 179, and 180 have been approved under OMB control number 0910–0016.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/FoodGuidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*. Use the FDA websites listed in the previous sentence to find the most current version of the guidance.

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31529 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0465, FDA–2022–D–0466, and FDA–2022–D–0467]

Draft Guidances Relating to Recommendations To Reduce the Risk of Transmission of Relevant Communicable Disease Agents and Diseases by Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of three

specific draft guidances for industry entitled ''Recommendations to Reduce the Risk of Transmission of Hepatitis B Virus (HBV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps);'' ''Recommendations to Reduce the Risk of Transmission of Hepatitis C Virus (HCV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps);'' and ''Recommendations to Reduce the Risk of Transmission of Human Immunodeficiency Virus (HIV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' These draft guidances are intended to update existing guidances and to assist establishments making donor eligibility determinations in understanding the requirements for determining donor eligibility, including donor screening and testing, for donors of HCT/Ps. These draft guidances are also intended to provide establishments making donor eligibility determinations with recommendations to reduce the risk of transmission of specific communicable disease agents and diseases, specifically, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV), by HCT/Ps.

DATES: Submit either electronic or written comments on the draft guidances by February 6, 2025 to ensure that the Agency considers your comment on these draft guidances before it begins work on the final versions of the guidances.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the dockets unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–0465 for ''Recommendations to Reduce the Risk of Transmission of Hepatitis B Virus (HBV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry;'' Docket No. FDA–2022–D–0466 for ''Recommendations to Reduce the Risk of Transmission of Hepatitis C Virus (HCV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry;'' and Docket No. FDA–2022–D–0467 for ''Recommendations to Reduce the Risk of Transmission of Human Immunodeficiency Virus (HIV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry.'' Received comments will be placed in the dockets and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the dockets to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket numbers, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidances to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidances may also be obtained by phone by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidances.

FOR FURTHER INFORMATION CONTACT: Victoria Wagman, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of three draft guidances entitled: ''Recommendations to Reduce the Risk of Transmission of Hepatitis B Virus (HBV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps);'' ''Recommendations to Reduce the Risk of Transmission of Hepatitis C Virus (HCV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps);'' and ''Recommendations to Reduce the Risk

of Transmission of Human Immunodeficiency Virus (HIV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' When finalized, these draft guidances will update existing guidance documents and assist establishments making donor eligibility determinations in understanding the requirements for determining donor eligibility, including donor screening and testing, for donors of HCT/Ps. When finalized, these specific draft guidances will also provide establishments making donor eligibility determinations with recommendations to reduce the risk of transmission of HBV, HCV, and HIV by HCT/Ps. Updates to existing guidance recommendations include but are not limited to: revising recommendations for donor screening that includes reducing certain time-based risk factors and conditions; assessing HCT/P donor eligibility using the same individual risk-based questions relevant to risk for every donor regardless of sex or gender, and for the draft guidance related to HIV, donor testing and screening for HIV–1 group O risk.

Based on FDA review of the available science, adequacy of available test methods, studies used to evaluate risk behaviors, and experiences with updated blood donor screening questions, FDA also recommends eliminating the HCT/P donor screening questions specific to men who have sex with men (MSM) and women who have sex with MSM and, instead recommends assessing HCT/P donor eligibility using the same individual risk-based questions relevant to HBV, HCV, and HIV risk for every donor regardless of sex or gender.

TABLE 1—THREE DRAFT GUIDANCES ISSUED FOR PUBLIC COMMENT

Docket No.	Draft guidance document title
FDA–2022–D–0465.	Recommendations to Reduce the Risk of Transmission of Hepatitis B Virus (HBV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry.
FDA–2022–D–0466.	Recommendations to Reduce the Risk of Transmission of Hepatitis C Virus (HCV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry.
FDA–2022–D–0467.	Recommendations to Reduce the Risk of Transmission of Human Immunodeficiency Virus (HIV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry.

At a later date, FDA intends to issue additional specific draft guidances with recommendations regarding specific communicable disease agents and diseases for donors of HCT/Ps as follows: (1) transmissible spongiform encephalopathy, (2) *Treponema pallidum* (syphilis), (3) *Chlamydia trachomatis* and *Neisseria gonorrhoeae,* (4) vaccinia virus, (5) West Nile virus, (6) human T-lymphotropic virus, (7) Cytomegalovirus, and (8) communicable disease risks associated with xenotransplantation.

The draft guidances, when finalized, are intended to supersede information regarding HBV, HCV, and HIV risk in the document entitled ''Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), Guidance for Industry,'' dated August 2007. Regarding HBV risk, the draft guidance is also intended to supersede the document entitled ''Use of Nucleic Acid Tests to Reduce the Risk of Transmission of Hepatitis B Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products, Guidance for Industry'' dated August 2016.

The three draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on ''Recommendations to Reduce the Risk of Transmission of Hepatitis B Virus (HBV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps);'' ''Recommendations to Reduce the Risk of Transmission of Hepatitis C Virus (HCV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps);'' and ''Recommendations to Reduce the Risk of Transmission of Human Immunodeficiency Virus (HIV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While these guidances contains no new collection of information, they do refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 1271.50 have been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 26, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31523 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0464]

Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance document entitled ''Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' This draft guidance document includes general information on determining eligibility for donors of HCT/Ps. In addition, FDA intends to issue separate guidance documents with recommendations regarding reducing the risk of transmission of specific communicable disease agents and diseases for donors of HCT/Ps. These guidance documents are intended to update an existing guidance.

DATES: Submit either electronic or written comments on the draft guidance by February 6, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–0464 for ''Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Victoria Wagman, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' This draft guidance document is intended to update an existing guidance document to assist establishments making donor eligibility determinations in understanding the requirements for determining donor eligibility, including donor screening and testing, for donors of HCT/Ps.

The draft guidance ''Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' includes general information on determining eligibility for donors of HCT/Ps. Updates to existing guidance recommendations include, but are not limited to, revised exceptions applicable to certain HCT/Ps, 21 CFR 1271.90 (81 FR 40517, June 22, 2016); clarifications surrounding the donor medical history interview; and additional considerations regarding specimens for donor testing to avoid false negative test results.

FDA intends to issue separate, additional guidance documents with recommendations regarding reducing the risk of transmission of specific communicable disease agents and diseases for donors of HCT/Ps as follows: human immunodeficiency virus, hepatitis B virus, hepatitis C virus, *Mycobacterium tuberculosis* (Mtb), sepsis, human transmissible spongiform encephalopathies, cytomegalovirus, *Chlamydia trachomatis* and *Neisseria gonorrhoeae,* human T-lymphotropic virus, *Treponema pallidum* (syphilis), vaccinia virus, West Nile virus, and communicable disease risk associated with xenotransplantation. Please note that FDA has withdrawn the 2018 guidance for industry ''Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products.'' FDA has determined that Zika virus (ZIKV) is no longer a relevant communicable disease agent or disease because the available evidence demonstrates that ZIKV no longer has sufficient incidence and/or prevalence to affect the potential HCT/P donor population.

The draft of the general guidance document and the associated specific guidance documents, when finalized, are intended to supersede the following guidance documents:

- ''Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), Guidance for Industry,'' dated August 2007;
- ''Use of Donor Screening Tests To Test Donors of Human Cells, Tissues and Cellular and Tissue-Based Products for Infection with *Treponema pallidum*

(Syphilis), Guidance for Industry'' dated September 2015;

• ''Use of Nucleic Acid Tests To Reduce the Risk of Transmission of Hepatitis B Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products, Guidance for Industry'' dated August 2016;

• ''Use of Nucleic Acid Tests To Reduce the Risk of Transmission of West Nile Virus from Living Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), Guidance for Industry'' dated September 2016 and corrected May 2017; and

• ''Revised Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products Who Have Received Human-Derived Clotting Factor Concentrates, Guidance for Industry'' dated November 2016.

When the general guidance and the associated specific guidances are finalized, FDA intends to collate information from the guidances and provide comprehensive lists of recommendations on the FDA website regarding conditions and behaviors that increase the donor's relevant communicable disease risk, examples of clinical evidence of relevant communicable disease, examples of physical evidence of relevant communicable disease or high-risk behavior associated with these diseases, disease agents for which all donors of HCT/Ps must be tested, and the types of tests we currently consider to be adequate and appropriate to meet the requirements in 21 CFR 1271.80(c). The comprehensive lists will cite to the applicable guidance(s) where the recommendations are provided.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 1271 have been approved under OMB control number 0910–0543.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 26, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31524 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–2707]

Validation of Certain In Vitro Diagnostic Devices for Emerging Pathogens During a Section 564 Declared Emergency; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Validation of Certain In Vitro Diagnostic Devices for Emerging Pathogens During a Section 564 Declared Emergency.'' The draft guidance describes general recommendations for the validation of in vitro diagnostic devices (IVDs) for emerging pathogens during an applicable declaration of public health emergency. This guidance and the associated template include the recommendations that apply to test data and information submitted in a pre-Emergency Use Authorization (EUA), an EUA request, or to a test offered as described in an applicable enforcement discretion policy. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by March 10, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–2707 for ''Validation of Certain In Vitro Diagnostic Devices for Emerging Pathogens During a Section 564 Declared Emergency.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential

with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Validation of Certain In Vitro Diagnostic Devices for Emerging Pathogens During a Section 564 Declared Emergency'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Toby Lowe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3416, Silver Spring, MD 20993–0002, 301–796–6512.

SUPPLEMENTARY INFORMATION:

I. Background

The guidance describes general recommendations for the validation of IVDs for emerging pathogens to help test manufacturers better prepare for future outbreaks by clarifying FDA's expectations for test validation during an applicable declaration under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb–3). Accurate and reliable IVDs are critical to the diagnosis, tracking, treatment, and interruption of transmission of infectious diseases during outbreaks, as well as for diagnosing and treating diseases or conditions caused by chemical, biological, radiological, or nuclear threats. These recommendations apply to test data and information submitted in a pre-EUA, an EUA request, or to a test offered as described in an applicable enforcement discretion policy. This draft guidance and the associated template address recommendations from two independent assessments of FDA's response to COVID–19. Specifically, FDA selected Booz Allen Hamilton to do such an independent assessment, which culminated in an October 2021 report, ''Emergency Use Authorization Assessment—Final Report'' (*https://www.fda.gov/media/152992/download*), that recommended FDA ''develop a framework for how to conduct validation of diagnostic tests for emerging pathogens in the setting of a declared PHE.'' Similarly, the Office of the Inspector General's September 2022 report, ''FDA Repeatedly Adapted Emergency Use Authorization Policies To Address the Need for COVID–19 Testing'' (*https://oig.hhs.gov/oei/reports/OEI-01-20-00380.pdf*), recommended that FDA ''develop a suite of EUA templates for future emergencies involving novel pathogens'' and ''expand and improve resources'' on the EUA process among other actions FDA has taken or is taking.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on Validation of Certain In Vitro Diagnostic Devices for Emerging Pathogens During a Section 564 Declared Emergency. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Validation of Certain In Vitro Diagnostic Devices for Emerging Pathogens During a Section 564 Declared Emergency'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00007020 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
''Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders''.	Emergency use authorization	0910–0595
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Use Devices; Humanitarian Device Exemption.	0910–0332
812	Investigational Device Exemption	0910–0078

21 CFR part; guidance; or FDA form	Topic	OMB control No.
860, subpart D	De Novo classification process	0910–0844
''Administrative Procedures for CLIA Categorization'' and ''Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices''.	CLIA Administrative Procedures; CLIA Waivers	0910–0607
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification.	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
50, 56	Protection of Human Subjects and Institutional Review Boards.	0910–0130

Dated: December 26, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31522 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–3863]

Recommendations To Reduce the Risk of Transmission of Mycobacterium Tuberculosis by Human Cells, Tissues, and Cellular and Tissue-Based Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for immediate implementation entitled ''Recommendations To Reduce the Risk of Transmission of *Mycobacterium Tuberculosis* (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' FDA is issuing this guidance to assist establishments that make donor eligibility determinations for donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps), with recommendations for screening donors for evidence of, and risk factors for, infection with *Mycobacterium tuberculosis* (Mtb), the organism that causes tuberculosis. The guidance also recommends additional steps that HCT/P establishments should take to reduce risk of transmission of Mtb until such time as appropriate FDA-licensed, approved, or cleared donor screening tests are available for use to test donors for Mtb infection. The guidance identifies Mtb as a relevant communicable disease agent or disease (RCDAD) and supplements the recommendations contained in other donor eligibility guidance documents for donors of HCT/Ps. This guidance is being issued to address the urgent public health need to reduce the risk of transmission of Mtb by HCT/Ps.

DATES: The announcement of the guidance is published in the **Federal Register** on January 7, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–3863 for ''Recommendations To Reduce the Risk of Transmission of *Mycobacterium Tuberculosis* (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting

of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see § 10.115(g)(5) (21 CFR 10.115(g)(5))).

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send two self-addressed adhesive labels to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jessica Gillum, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for immediate implementation entitled ''Recommendations To Reduce the Risk of Transmission of *Mycobacterium Tuberculosis* (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' FDA is issuing this guidance to provide establishments that make donor eligibility determinations for donors of HCT/Ps with recommendations for screening for evidence of, and risk factors for, infection with Mtb, the organism that causes tuberculosis. The guidance also recommends additional steps that HCT/P establishments should take to reduce risk of transmission of Mtb until such time as appropriate FDA-licensed, approved, or cleared donor screening tests are available for use to test donors for Mtb infection.

In addition, this guidance identifies Mtb as an RCDAD as defined in 21 CFR 1271.3(r)(2) and supplements the recommendations contained in other donor eligibility guidance documents for donors of HCT/Ps.

In 2021 and 2023, multistate outbreaks of Mtb in the United States were linked to transplantation of bone allograft products and resulted in significant morbidity and mortality. Because Mtb transmission can occur from HCT/P donors with unrecognized and undiagnosed tuberculosis infection, these circumstances demand heightened awareness when screening donors of HCT/Ps.

We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). We made this determination because of the urgent public health need to provide recommendations to industry to reduce the risk of transmission of Mtb by HCT/Ps. Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA's GGP.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of another immediately in effect guidance entitled ''Recommendations To Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' with recommendations to reduce the risk of transmission of disease agents associated with sepsis, including mycobacterial agents such as Mtb, which can be a cause of sepsis.

The guidance represents the current thinking of FDA on ''Recommendations To Reduce the Risk of Transmission of *Mycobacterium Tuberculosis* (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR 1271 relating to HCT/Ps, including establishing and maintaining records, investigation and reporting of adverse actions and documentation of methods used in facilities related to HCT/Ps, which, includes but not limited to donor screening, donor testing, and labeling have been approved under OMB control number 0910–0543.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31544 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–3334]

Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway.'' For drugs granted accelerated approval, sponsors conduct confirmatory studies that must be completed postapproval to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. This draft guidance describes FDA's interpretation of the term ''underway'' and discusses policies for implementing this requirement, including factors FDA intends to consider when determining whether a confirmatory trial is underway prior to accelerated approval.

DATES: Submit either electronic or written comments on the draft guidance by March 10, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by March 10, 2025.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–3334 for ''Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Tamy Kim, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2206, Silver Spring, MD 20993–0002, 301–796–1125, or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911, or Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993–0002, 240–402–8926 or 301–796–2500.

With regard to the proposed collection of information: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway.'' For drugs granted accelerated approval, sponsors have been required to conduct confirmatory studies postapproval to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In the Consolidated Appropriations Act, 2023 (CAA), Congress amended section 506(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356(c)), to provide additional authorities to help ensure timely completion of such trials, including that FDA ''may require, as appropriate, a study or studies to be underway prior to approval, or within a specified time period after the date of approval, of the applicable product. This draft guidance, when finalized, will describe FDA's interpretation of the term ''underway'' and policies for implementing this requirement, including factors FDA intends to consider when determining whether a confirmatory trial is underway prior to an accelerated approval action.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Accelerated Approval and Considerations for Determining Whether a Required Post-Marketing Clinical Trial is Underway.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the

requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway

OMB Control Number 0910–0001—Revision

As noted, section 506 of the FD&C Act was modified by section 3210 of the CAA, which granted FDA additional authorities with additional obligations regarding the accelerated approval pathway. Among other revisions, section 3210 of the CAA provides statutory authority to help ensure timely completion of confirmatory trials of accelerated approval products, including that FDA may require as appropriate, a confirmatory study or studies to be underway prior to approval or within a specified time period after the date of approval of the product. The CAA also requires sponsors to submit postmarketing reports to FDA on the progress of required confirmatory trials approximately every 180 days. This draft guidance describes FDA's policies for implementing this statutory authority. FDA will use the reports to monitor the progress of confirmatory trials and take action, if necessary. The information is needed to support FDA's efforts to protect the health of users of drugs approved under accelerated approval. We are requesting approval to revise the statutory authority reference in approved OMB control numbers 0910–0001 and 0910–0338 to include section 3210 of the CAA.

Description of Respondents: Respondents to this information collection are sponsors of human drug and biological products.

Burden Estimate: We reviewed the statutory authority granted by section 3210 of the CAA as well as our existing statutory authority and regulations. Section 506B of the FD&C Act (21 U.S.C. 356b), and implementing regulations in §§ 312.20, 314.81 and 601.70 (21 CFR 312.20, 314.81 and 601.70), provide for the submission of postmarket study reports, requiring sponsors of approved drugs and biological products to report to FDA on the progress of their postmarketing study commitments, including reports on required studies, clinical trials, and agreed upon commitments.

We tentatively conclude that the change in our statutory authority adds no further information collection requirements and imposes no further burden beyond what is already required in our statutes and regulations and included in the approved ICRs for reporting the status of postmarketing study commitments.

This draft guidance also refers to previously approved FDA collections of information. The collections of information in 21 CFR parts 50 and 56 for protection of human subjects and institutional review boards have been approved under OMB control number 0910–0130. The collections of information in 21 CFR part 312 for submission of investigational new drug applications, conduction of clinical trials and good clinical practice, meetings for design and implementation of drug development plans, and reports of data for confirmatory trials have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 for submission of new drug applications and abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information in §§ 312.20, 314.81 and 601.70 for submission of postmarketing reports including accelerated approval clinical benefit studies have been approved under OMB control numbers 0910–0014, 0910–0001, and 0910–0338. The collections of information in 21 CFR parts 601 and 610 for submission of biologics license applications have been approved under OMB control number 0910–0338. The collections of information for expedited pathways for development programs of drugs and biologics for serious conditions have been approved under OMB control number 0910–0765.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31527 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–2402]

Considerations for Including Tissue Biopsies in Clinical Trials; Draft Guidance for Industry, Investigators, Institutions, and Institutional Review Boards; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) and the Office for Human Research Protections (OHRP) are announcing the availability of a draft guidance for industry, clinical investigators, institutions, and institutional review boards (IRBs) entitled ''Considerations for Including Tissue Biopsies in Clinical Trials.'' This guidance provides recommendations regarding considerations for tissue biopsies that may be conducted in adults and in children as part of clinical trials evaluating investigational medical products and/or that are conducted or

supported by the Department of Health and Human Services (HHS).

DATES: Submit either electronic or written comments on the draft guidance by March 10, 2025. to ensure that the Agency and OHRP consider your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–2402 for ''Considerations for Including Tissue Biopsies in Clinical Trials.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or to the Office for Human Research Protections, Division of Policy and Assurances, 1101 Wootton Pkwy., Suite 200, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jennifer Gao, Oncology Center of Excellence/Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2135, Silver Spring, MD 20993–0002, 301–796–1397; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911; or Christina Savisaar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G221, Silver Spring, MD 20993–0002, 301–796–6404; or Natalie Klein, Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Pkwy., Suite 200, Rockville, MD 20852, 240–453–6900 or 866–447–4777.

SUPPLEMENTARY INFORMATION:

I. Background

FDA and OHRP are announcing the availability of a draft guidance for industry, clinical investigators, institutions, and IRBs entitled ''Considerations for Including Tissue Biopsies in Clinical Trials.'' This guidance is intended to assist industry, clinical investigators, institutions, and IRBs in understanding considerations for tissue biopsies that may be conducted in adults and in children as part of clinical trials that evaluate investigational medical products and/or that are conducted or supported by HHS. For the purposes of this guidance, a biopsy is a procedure that involves acquisition of tissue from a trial participant as part of a clinical trial protocol.

Although biopsies inherently include varying degrees of risk, in some circumstances, biopsied tissue(s) may be the only way to obtain information that is necessary to answer questions of interest in a clinical trial, such as to determine trial eligibility or to evaluate treatment effects. In general, when biopsies are to be conducted for evaluation of non-key secondary endpoint(s) and/or exploratory endpoints or for unspecified future

research uses, they should not be required and instead should be optional.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA and OHRP on ''Considerations for Including Tissue Biopsies in Clinical Trials.'' It does not establish any rights for any person and is not binding on FDA, OHRP, or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information related to the protection of human subjects under 21 CFR part 50 and the IRB under 21 CFR part 56 have been approved under OMB control number 0910–0130; the collection of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 312, including Form FDA 1572, have been approved under OMB control number 0910–0014 and the collections of information in the guidance document, ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' have been approved under OMB control number 0910–0756. The collections of information in 21 CFR part 11 have been approved under OMB control number 0910–0303. The collections of information in 45 CFR part 46 and the final rule entitled, ''Federal Policy for the Protection of Human Subjects'' (known as the Common Rule), have been approved under OMB control number 0990–0260.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31536 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; A Solicitation of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) for Small Business Innovation Research (SBIR) Contract Proposals (PHS 2025–1), NIH/NIAID 142—Adjuvant Development for Vaccines.

Date: January 30–31, 2025.

Time: 9:00 a.m. to 6:00 p.m.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22, Rockville, MD 20892 (Video Assisted Meeting).

Agenda: To review and evaluate contract proposals.

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 20892, 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: January 2, 2025.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–00099 Filed 1–6–25; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; HHS–NIH–CDC–SBIR PHS 2025–1 Phase I and Fast Track: Devices and Materials-Based Platforms for the Delivery of Broadly Neutralizing Antibodies (Topic 138).

Date: January 24, 2025.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E71, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Samita S. Andreansky, 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 3E71, Rockville, MD 20892, 240–669–2915, *samita.andreansky@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: January 2, 2025.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–00101 Filed 1–6–25; 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: Microbiology, Infectious Diseases and AIDS Initial Review Group; Microbiology and Infectious Diseases Research Study Section.

Date: February 5–6, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

ADDRESS: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G74, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Hailey P. Weerts, 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 3G74, Rockville, MD 20852, (240) 669–5931, *hailey.weerts@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: January 2, 2025.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–00110 Filed 1–6–25; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; HHS–NIH–CDC–SBIR PHS 2025–1 Development of Diagnostics for Mycoplasma genitalium Infection (Topic 143).

Date: January 27–29, 2025.

Time: 9:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 903 South 4th Street, RML 31/3118, Hamilton, MT 59840 (Video Assisted Meeting).

Contact Person: Dylan P. Flather, Ph.D., Scientific Review Officer, Natl Institute of Allergy & Infectious Diseases, National Institutes of Health, 903 S. 4th Street, RML 31/31118A, Hamilton, MT 59840, (406) 802–6209, *dylan.flather@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: January 2, 2025.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–00106 Filed 1–6–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Preparation and Distribution of Research Drug Products.

Date: February 5, 2025.

Time: 3:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate contract proposals.

Address: National Institute of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Gagan Deep Bajaj, Scientific Review Officer, National Institute on Drug Abuse, NIH, Scientific Review Branch, 11601 Landsdown Street, 3WF Room 09A01, Bethesda, MD 20892, (301) 402–6965, *gagan.bajaj@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: January 2, 2025.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–00108 Filed 1–6–25; 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 Research Education Program (R25 Clinical Trial Not Allowed).

Date: January 24, 2025.

Time: 1:00 p.m. to 5:00 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 3G21A, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Shiv A. Prasad, 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 3G21A, Rockville, MD 20892, *shiv.prasad@nih.gov*, (240) 627–3219.

(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: January 2, 2025.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–00104 Filed 1–6–25; 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 Implementation Cooperative Agreement (U01 Clinical Trial Required).

Date: February 7, 2025.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Stephen A. Gallo, 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, MSC 9834, Rockville, MD 20852, (240) 669–2858, *steve.gallo@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: January 2, 2025.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–00103 Filed 1–6–25; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; HHS–NIH–CDC–SBIR PHS 2025–1 Phase I and Fast Track: Rapid Diagnostic Assays for Self-Monitoring of Acute or Rebound HIV–1 Infection (Topic 139).

Date: January 30–31, 2025.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G34, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Vishakha Sharma, 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 3G34, Rockville, MD 20892, 301–761–7036, *vishakha.sharma@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: January 2, 2025.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–00102 Filed 1–6–25; 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: Allergy, Immunology, and Transplantation Research Committee.

Date: February 19–20, 2025.

Time: 10:00 a.m. to 6:00 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 3G51, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Thomas F. Conway, 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 3G51, Rockville, MD 20892, 240–507–9685, *thomas.conway@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: January 2, 2025.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–00111 Filed 1–6–25; 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 Implementation Cooperative Agreement (U01 Clinical Trial Required).

Date: January 28, 2025.

Time: 10:00 a.m. to 12:00 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 3G56, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Maryam Rohani, 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 3G56, Rockville, MD 20892, (301) 761–6656, *maryam.rohani@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: January 2, 2025.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–00105 Filed 1–6–25; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; HHS–NIH–CDC–SBIR PHS 2025–1 Phase I and Phase II: Adjuvant Discovery and Down-Selection for Vaccines against Infectious and Immune-Mediated Diseases (Topic 140).

Date: February 6–7, 2025.

Time: 12:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G58, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Anuja Mathew, 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 3G58, Rockville, MD 20892, 301–761–6911, *anuja.mathew@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: January 2, 2025.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–00100 Filed 1–6–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR: Enhancing Mechanistic Research on Precision Probiotic Therapies.

Date: January 31, 2025.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jonathan Michael Peterson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 867–5309, *jonathan.peterson@nih.gov*.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Skeletal Biology Structure and Regeneration Study Section.

Date: February 4–5, 2025.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Yanming Bi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, (301) 451–0996, *ybi@csr.nih.gov*.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Surgery, Anesthesiology and Trauma Study Section.

Date: February 5–6, 2025.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Weihua Luo, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5114, MSC 7854, Bethesda, MD 20892, (301) 435–1170, *luow@csr.nih.gov*.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neuroscience of Basic Visual Processes Study Section.

Date: February 5–6, 2025.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Kirk Thompson, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5184, MSC 7844, Bethesda, MD 20892, 301–435–1242, *kgt@mail.nih.gov*.

Name of Committee: Vascular and Hematology Integrated Review Group; Atherosclerosis and Vascular Inflammation Study Section.

Date: February 6–7, 2025.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Natalia Komissarova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, MSC 7846, Bethesda, MD 20892, (301) 435–1206, *komissar@mail.nih.gov*.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Genomics, Computational Biology and Technology Study Section.

Date: February 6–7, 2025.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Methode Bacanamwo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2200, Bethesda, MD 20892, 301–827–7088, *methode.bacanamwo@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 2, 2025.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–00107 Filed 1–6–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Voice Speech and Language Fellowship Review.

Date: February 14, 2025.

Time: 11:00 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Meeting Format: Virtual Meeting.

Contact Person: Sonia Elena Nanescu, Ph.D., Scientific Review Officer, Division of Extramural Activities, NIDCD, NIH, 6001 Executive Blvd., Suite 8300, Bethesda, MD 20892, (301) 496–8683, *sonia.nanescu@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: January 2, 2025.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–00109 Filed 1–6–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Statement of Organization, Functions, and Delegations of Authority

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) All of Us Research Program has modified their organizational structure. The new organizational structure was approved by the Secretary of Health and Human Services on December 19, 2024.

FOR FURTHER INFORMATION CONTACT: Tara A. Schwetz, Director, Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI); 9000 Rockville Pike, Bethesda, MD 20892; 301–402–9852.

SUPPLEMENTARY INFORMATION: Part N, National Institutes of Health (NIH), of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (HHS) (42 U.S.C. 281(c); section 401(c) of the Public Health Service Act, as amended) is amended as set forth below to reflect the reorganization of the National Institute of Health, Office of the Director, by abolishing (1) the *All of Us* Research Program in the NIH Office of the Director, (2) establishing the *All of Us* Research Program within the Division of Program Coordination, Planning and Strategic Initiatives (DPCPSI), (3) establish the Environmental Influences on Child Health Outcomes Program Office (EHCO), and (4) the revised functional statement of DPCPSI.

Section N–B, *Organization and Functions,* under the heading *National Institute of Health (N, formerly HN), Office of the Director (NA, formerly HNA)* is amended as follows:

(1) In the *Office of the Director (NA, formerly HNA)* remove the following:

All of Us Research Program Office (NAK, formerly HNAK). (1) Oversees the design, development, implementation, and evaluation of the *All of Us* Research Program Office, the largest and most diverse research cohort of its kind, to foster a new era of medicine in which researchers, providers, and patients work together to develop individualized care by supporting research into the complex factors promoting health and treatment to cure disease.

Office of the Chief Executive Officer (NAK1, formerly HNAK1). (1) Provides leadership for the *All of Us* Research Program; (2) manages and directs executive-level activities and functions; (3) provides policy guidance and overall operational coordination for the organizational units within the All of Us Research Program; (4) supports and coordinates research projects through Other Transaction (OT) Authority, research grants, contracts, and other mechanisms; (5) initiates, develops, manages, and maintains collaborative relationships and partnerships with other Federal and non-Federal organizations, academia, industry, participants, and patients; and (6) provides leadership and oversight to the *All of Us* Research Program Consortium.

Division of Cohort Development (NAK3, formerly HNAK3). (1) Oversees planning, implementation, and evaluation of all cohort development activities, including the enrollment and retention of diverse participants activities for the *All of Us* Research Program; (2) provides oversight for the biospecimen collection enterprise, including tissue accrual, biospecimen quality and distribution, data generation and analysis, in coordination with the NIH and other Federal partners; (3) oversees a collaborative and integrated network of awardees including health care provider organizations, a direct volunteer network, and a biobank; and

(4) assesses risk management issues, such as onsite inspections, providing reports and recommendations as needed.

Division of Technology and Platform Development (NAK4, formerly HNAK4). (1) Oversees the development, operations and management of participant and researcher facing platforms and tools; (2) provides strategic insight for innovative approaches and methods for computational dynamic modeling and complexity theory; (3) advises, plans and directs the continuous modernization of infrastructure to ensure data integrity, security, connectivity and operability across the Program platform; (4) facilitates the development of state-of-the-art data collection, data systems and structures to ensure rapid, reliable, interoperable, scalable and secure systems responsive to research; (5) provides leadership, management, and oversight of the Information Systems Security (JSS) activities and ensures consistency with legislation, regulations, and NIH and other Federal policies, including the Federal Information Security Management Act (FISMA), Federal Managers Financial Integrity Act (FMFIA), and the PMI Privacy and Trust Principles, and PMI Data Security Policy Principles and Framework.

Division of Communications (NAK5, formerly HNAK5). (1) Advances the public face of the *All of Us* Research Program by providing leadership, direction, and implementation for communications policies, plans, and products in support of the program's mission and priorities; (2) oversees media plans and website development and implementation for the program and its consortium; and (3) develops content for a variety of communications resources.

Division of Engagement and Outreach (NAK6, formerly HNAK6). (1) Provides strategic direction for outreach and engagement with stakeholders including participants, communities, health care providers, and researchers; (2) implements and evaluates ongoing outreach and engagement efforts to refine the program's approach and identify new needs; (3) implements novel approaches for long-term engagement of diverse populations; and (4) collaborates and coordinates the sharing of participant feedback and perspectives throughout the *All of Us* Research Program and with the broader research community.

Division of User Experience (NAK7, formerly HNAK7). (1) Provides strategic direction for outreach and engagement with stakeholders including participants, communities, health care providers, and researchers; (2) implements and evaluates ongoing outreach and engagement efforts to refine the program's approach and identify new needs; (3) implements novel approaches for long-term engagement of diverse populations; and (4) collaborates and coordinates the sharing of participant feedback and perspectives throughout the *All of Us* Research Program and with the broader research community.

(2) In the *Division of Program Coordination, Planning, and Strategic Initiatives (NAW, formerly HNAW)* insert the following:

All of Us Research Program Office (NAWK, formerly HNAWK). (1) Oversees the design, development, implementation, and evaluation of the *All of Us* Research Program Office, the largest and most diverse research cohort of its kind, to foster a new era of medicine in which researchers, providers, and patients work together to develop individualized care by supporting research into the complex factors promoting health and treatment to cure disease.

Office of the Chief Executive Officer (NAWK1, formerly HNAWK1). (1) Provides leadership for the *All of Us* Research Program; (2) manages and directs executive-level activities and functions; (3) provides policy guidance and overall operational coordination for the organizational units within the All of Us Research Program; (4) supports and coordinates research projects through Other Transaction (OT) Authority, research grants, contracts, and other mechanisms; (5) initiates, develops, manages, and maintains collaborative relationships and partnerships with other Federal and non-Federal organizations, academia, industry, participants, and patients; and (6) provides leadership and oversight to the *All of Us* Research Program Consortium.

Division of Medical and Scientific Research (NAWK2, formerly HNAWK2). (1) Provides clinical and scientific direction for the complex and highly varied activities related to the *All of Us* Research Program; (2) serves as the medical liaison to Institute/Center leadership within the NIH and to the partnering health care provider organizations that are part of the *All of Us* Research Program Consortium; (3) oversees the administration of clinical projects supported by the *All of Us* Research Program; (4) oversees the development and delivery of genomics information; and (5) supports the advancement of regulatory science in the precision medicine era.

Division of Cohort Development (NAWK3, formerly HNAWK3). (1) Oversees planning, implementation, and evaluation of all cohort development activities, including the enrollment and retention of diverse participants activities for the *All of Us* Research Program; (2) provides oversight for the biospecimen collection enterprise, including tissue accrual, biospecimen quality and distribution, data generation and analysis, in coordination with the NIH and other Federal partners; (3) oversees a collaborative and integrated network of awardees including health care provider organizations, a direct volunteer network, and a biobank; and (4) assesses risk management issues, such as onsite inspections, providing reports and recommendations as needed.

Division of Technology and Platform Development (NAWK4, formerly HNAWK4). (1) Oversees the development, operations and management of participant and researcher facing platforms and tools; (2) provides strategic insight for innovative approaches and methods for computational dynamic modeling and complexity theory; (3) advises, plans and directs the continuous modernization of infrastructure to ensure data integrity, security, connectivity and operability across the Program platform; (4) facilitates the development of state-of-the-art data collection, data systems and structures to ensure rapid, reliable, interoperable, scalable and secure systems responsive to research; (5) provides leadership, management, and oversight of the Information Systems Security (JSS) activities and ensures consistency with legislation, regulations, and NIH and other Federal policies, including the Federal Information Security Management Act (FISMA), Federal Managers Financial Integrity Act (FMFIA), and the PMI Privacy and Trust Principles, and PMI Data Security Policy Principles and Framework.

Division of Communications (NAWK5, formerly HNAWK5). (1) Advances the public face of the *All of Us* Research Program by providing leadership, direction, and implementation for communications policies, plans, and products in support of the program's mission and priorities; (2) oversees media plans and website development and implementation for the program and its consortium; and (3) develops content for a variety of communications resources.

Division of Engagement and Outreach (NAWK6, formerly HNAWK6). (1) Provides strategic direction for outreach and engagement with stakeholders

including participants, communities, health care providers, and researchers; (2) implements and evaluates ongoing outreach and engagement efforts to refine the program's approach and identify new needs; (3) implements novel approaches for long-term engagement of diverse populations; and (4) collaborates and coordinates the sharing of participant feedback and perspectives throughout the *All of Us* Research Program and with the broader research community.

(3) In the *Division of Program Coordination, Planning, and Strategic Initiatives (NAW, formerly HNAW)* insert the following:

Environmental Influences on Child Health Outcome (NAWL, formerly HNAWL). (1) Provides scientific leadership for initiatives to catalyze observational and interventional research to enhance the health of children for generations to come; (2) provides support for longitudinal observational research and a Pediatric Clinical Trials Network for interventional research; (3) facilitates work of grantees to implement innovative paradigms for research and provides programmatic oversight, scientific guidance, organizational infrastructure, and resources to grantees; and (4) engages with external and internal partners to facilitate bidirectional communication about research gaps and to disseminate findings.

(4) In the *Division of Program Coordination, Planning, and Strategic Initiatives (NAW, formerly HNAW)* revise the functions as follows:

Division of Program Coordination, Planning, and Strategic Initiatives (NAW, formerly HNAW). (1) Identifies and reports on research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis and would benefit from conducting or supporting additional research that involves collaboration between two or more Institutes and Centers (ICs), or would otherwise benefit from strategic coordination and planning; (2) coordinates research and activities related to AIDS, behavioral and social sciences, women's health, disease prevention, research infrastructure, sexual and gender minorities, tribal health, data science, dietary supplements, nutrition, and the *All of Us* Research and Environmental influences on Child Health Outcomes (ECHO) programs, and INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE (INCLUDE) project; (3) uses resources (databases, analytic tools, and methodologies) and develops specifications for new resources, when needed, to conduct assessments based on NIH and other databases in support of portfolio analyses and priority setting in scientific areas of interest across NIH; (4) serves as a resource for portfolio management at the programmatic level; (5) ensures that NIH addresses important areas of emerging scientific opportunities and public health challenges effectively; and (6) plans, conducts, and coordinates NIH-wide planning and evaluation activities and reporting such as that required by the Government Performance and Results Act (GPRA).

Delegations of Authority Statement: All delegations and redelegations of authority to officers and employees of NIH that were in effect immediately prior to the effective date of this amendment and are consistent with this amendment shall continue in effect, pending further redelegation.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2025–00080 Filed 1–3–25; 11:15 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

[Docket ID FEMA–2014–0022]

Technical Mapping Advisory Council; Meeting

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice of open Federal advisory committee meeting.

SUMMARY: The Federal Emergency Management Agency (FEMA) Technical Mapping Advisory Council (TMAC) will hold a virtual meeting on Friday, January 24, 2025. The meeting will be open to the public via a Microsoft Teams Video Communications link.

DATES: The TMAC will meet on Friday, January 24, 2025, from 8 a.m. to 5 p.m. eastern time (ET). Please note that the meeting will close early if the TMAC has completed its business.

ADDRESSES: The meeting will be held virtually using the following Microsoft Teams Video Communications link (*https://teams.microsoft.com/l/meetup-join/19%3ameeting_Mzc5MWE1ZTktYzIzOS00NjM5LWFiODEtMWY2OTE4YWMwMmE2%40thread.v2/0?context=%7b%22Tid%22%3a%22ff59a812-dbf7-4b26-b9fd-bb02aaa6c719%22%2c%22Oid%22%3a%22b626e4e6-c859-4772-9920-c60d2aa40277%22%7d*). Members of the public who wish to attend the virtual meeting must register in advance by sending an email to *FEMA-TMAC@fema.dhs.gov* (Attn: Brian Koper) by 5 p.m. ET on Tuesday, January 21, 2025.

To facilitate public participation, members of the public are invited to provide written comments on the issues to be considered by the TMAC, as listed in the **SUPPLEMENTARY INFORMATION** caption below. Associated meeting materials will be available upon request on Wednesday, January 22, 2025. To receive a copy of any relevant materials, please send the request to: *FEMA-TMAC@fema.dhs.gov* (Attn: Brian Koper). Written comments to be considered by the committee at the time of the meeting must be submitted and received by Tuesday, January 21, 2025, 5 p.m. ET identified by Docket ID FEMA–2014–0022, and submitted by the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email:* Address the email to *FEMA-TMAC@fema.dhs.gov.* Include the docket number in the subject line of the message. Include name and contact information in the body of the email.

Instructions: All submissions received must include the words ''Federal Emergency Management Agency'' and the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided. You may wish to review the Privacy and Security Notice via a link on the homepage of *http://www.regulations.gov.*

Docket: For docket access to read background documents or comments received by the TMAC, go to *http://www.regulations.gov* and search for the Docket ID FEMA–2014–0022.

A public comment period will be held on Friday, January 24, 2025, from 1 p.m. to 1:30 p.m. ET. The public comment period will not exceed 30 minutes. Please note that the public comment period may end before the time indicated, following the last call for comments. Contact the individual listed below to register as a speaker by Tuesday, January 21, 2025, 5 p.m. ET. Please be prepared to submit a written version of your public comment by Thursday, January 23, 2025, 5 p.m. ET.

FEMA is committed to ensuring all participants have equal access regardless of disability status. If you require reasonable accommodation to fully participate due to a disability,

please contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** caption as soon as possible.

FOR FURTHER INFORMATION CONTACT: Brian Koper, Designated Federal Officer for the TMAC, FEMA, 400 C St. SW, Washington, DC 20472, telephone 202–646–3085, and email *brian.koper@fema.dhs.gov.* The TMAC website is: *https://www.fema.gov/flood-maps/guidance-partners/technical-mapping-advisory-council.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the *Federal Advisory Committee Act,* Public Law 117–286, 5 U.S.C. ch. 10.

In accordance with the *Biggert-Waters Flood Insurance Reform Act of 2012,* the TMAC makes recommendations to the FEMA Administrator on: (1) how to improve, in a cost-effective manner, the (a) accuracy, general quality, ease of use, and distribution and dissemination of flood insurance rate maps and risk data; and (b) performance metrics and milestones required to effectively and efficiently map flood risk areas in the United States; (2) mapping standards and guidelines for (a) flood insurance rate maps, and (b) data accuracy, data quality, data currency, and data eligibility; (3) how to maintain, on an ongoing basis, flood insurance rate maps and flood risk identification; (4) procedures for delegating mapping activities to State and local mapping partners; and (5) (a) methods for improving interagency and intergovernmental coordination on flood mapping and flood risk determination, and (b) a funding strategy to leverage and coordinate budgets and expenditures across Federal agencies. Furthermore, the TMAC is required to submit an annual report to the FEMA Administrator that contains: (1) a description of the activities of the Council; (2) an evaluation of the status and performance of flood insurance rate maps and mapping activities to revise and update Flood Insurance Rate Maps; and (3) a summary of recommendations made by the Council to the FEMA Administrator.

Agenda: The purpose of this meeting is for the TMAC members to discuss and vote on the content of the 2024 TMAC Annual Report. Any related materials will be available upon request prior to the meeting to provide the public with an opportunity to review the materials. The full agenda and related meeting materials will be available upon request by Wednesday, January 22, 2025. To receive a copy of any relevant materials, please send the request to: *FEMA-TMAC@fema.dhs.gov* (Attn: Brian Koper).

Nicholas A. Shufro,

Assistant Administrator (Acting), Risk Analysis, Planning & Information Directorate, Resilience, Federal Emergency Management Agency.

[FR Doc. 2025–00009 Filed 1–6–25; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7082–N–14]

60-Day Notice of Proposed Information Collection: Continuum of Care (CoC) Program Homeless Assistance Grant Application; OMB Control No: 2506–0112

AGENCY: Office of Community Planning and Development, (HUD).

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date: March 10, 2025.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection can be sent within 60 days of publication of this notice to *www.regulations.gov.* Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and can be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000; telephone (202) 402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information.

FOR FURTHER INFORMATION CONTACT: Robert Waters, Senior Program Specialist, Office of Special Needs Assistance Programs, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Robert at *Robert.P.Waters@hud.gov,* telephone (202) 402–4494. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* Copies of available documents submitted to OMB may be obtained from Mr. Waters or Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Continuum of Care (CoC) Program Homeless Assistance Grant Application.

OMB Approval Number: 2506–0112.

Type of Request: Extension of currently approved collection.

Description of the need for the information and proposed use: This submission is to request an extension of an existing collection in use with OMB Control Number 2506–0112, for the Recordkeeping for HUD's Continuum of Care Program grant application.

The CoC Consolidated Application has three parts: the CoC Application, CoC Priority Listing that lists all project applications with a rank number determined by CoCs in their local competition process, and Project Applications. HUD requires the submission of CoC applications from Collaborative Applicants to capture information related to the CoC's overall performance toward addressing homelessness (*e.g.,* reducing the number of homelessness, increasing income), coordination with other federal and non-federal partners, planning process (*e.g.,* reducing homelessness, length of time homeless), and other criteria required by the statute and current Administration policies. The information provided in CoC applications is reviewed and scored by HUD to determine the order in which HUD will select projects based on the ranking communicated in the CoC Priority Listing. The CoC Priority Listing collection notifies HUD if CoCs are reallocating current projects to create new projects and most importantly, to rank project applications with a unique number for funding consideration by HUD and determines the order in which projects are selected in order of each CoC. Project applications collect information for eligibility and quality threshold review to determine suitability for funding consideration. Successful project applications selected

for award receiving funding to carry out the activities approved by HUD. The statutory and regulatory requirements related to the CoC Program and applicable supplementary documents are located on the CoC Program page on HUD's website on HUD's website.

Respondents (*i.e.,* affected public): Nonprofit organizations, states, local governments, and instrumentalities of state and local governments, Indian Tribes, Tribally Designated Housing Entities (TDHEs) (as defined in section 4 of the Native American Housing Assistance and Self-Determination Act of 1996 (25 U.S.C. 4103)), and Public Housing Agencies (PHAs), as such term is defined in 24 CFR 5.100.

Information Collection/Form Number: Information is collected via the electronic e-snaps application system.

Estimated Number of Respondents: 405.

Estimated Number of Responses: 405.

Frequency of Response: Annually.

Responses Per Annum: 405.

Average Hours per Response: See chart.

Total Estimated Burdens: See chart; however, the information included in the chart below is subject to change due to: (1) increase or decrease, based on the number of CoCs due to CoC mergers, splits, or creation of new CoCs; and (2) changes may occur annually in the number of project applicants due to new project applicants applying for first-time funding, expiring new projects becoming eligible for first-time renewal, and other existing project applicants deciding to no longer apply for funds.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
CoC Consolidated Application	405	1	405	84	34,020	43.55	$1,481,571.00
Project Applications	9,740	1	9,740	8.3	80,842	43.55	3,520,669.1
Total	10,145	1	10,145				5,002,240.1

The total number of respondents is subject to change annually due to CoCs merging or splitting and with newly created CoCs due to authorizing language expanding eligibility (*e.g.,* FY 2021 appropriations language authorizing the Indian Tribes and TDHEs eligibility to form CoCs, submit CoC Consolidated applications, and project applications).

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Marion M. McFadden,

Principal Deputy Assistant Secretary for Community Planning and Development.

[FR Doc. 2025–00077 Filed 1–6–25; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7090–N–10]

60-Day Notice of Proposed Information Collection: Stepped and Tiered Rent Demonstration Evaluation; OMB Control No.: 2528–0339

AGENCY: Office of Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* March 10, 2025.

ADDRESSES: Interested persons are to submit comments regarding this proposal.

Written comments and recommendations for the proposed information collection can be submitted within 60 days of publication of this notice to *www.regulations.gov.* Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and can be sent to: Anna Guido, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000 or email at *PaperworkReductionActOffice@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Anna Guido, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email; *Anna.P.Guido@hud.gov;* telephone (202) 402–5535 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Stepped and Tiered Rent Demonstration Evaluation, Phase 2.

OMB Approval Number: 2528–0339.

Type of Request: Revision of currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: HUD has selected 10 Public Housing Agencies (PHAs) to participate in the second cohort of the Moving to Work (MTW) Expansion, Stepped and Tiered Rent Demonstration (STRD). These PHAs are implementing an alternative rent policy (a stepped rent or tiered rent) that intends to reduce PHA administrative burden and increase economic self-sufficiency of assisted households. Five PHAs are implementing a stepped rent and five PHAs are implementing a tiered rent. HUD's Office of Policy Development and Research (PD&R) is evaluating the impacts of those alternative rent policies, using a randomized controlled trial. The evaluation will rely on data from a variety of sources, including new information collection efforts proposed in this Notice. HUD contracted with MDRC to conduct the first phase of the evaluation, including random assignment, baseline data collection, and monitoring PHA implementation, and has now contracted with MDRC to conduct the second phase of the evaluation, including further administrative baseline data collection and follow-up data collection for the first three years of the six-year demonstration.

This **Federal Register** notice is seeking to extend and build upon previously approved data collection activities. For the second phase (Phase 2) of the evaluation, additional interviews with PHA staff will be conducted to understand their experiences with the alternative rent policies and costs associated with administering the alternative rent rules, and a 30-month follow-up survey will be fielded to study participants to assess the effects of the alternative rent policies on key outcomes that cannot be captured with administrative records, including material hardship. In addition to collecting these data, the STRD project will continue monitoring the implementation of the alternative rent rules and collecting PHA records for this purpose. Data collected is being used to estimate the effects of the alternative rent rules on employment, earnings, housing subsidy, and other key outcomes.

Member of Affected Public: Public housing agency administrators/staff managing or implementing the new rent policy and participants enrolled in the STRD study.

Estimated Number of Respondents: Interviews with PHA staff will have an estimated 120 respondents. Additional data collection from PHA staff will have an estimated 40 respondents. The survey of study participants will be fielded to 8,000 individuals and the response rate is expected to be 60%, so the number of estimated respondents is 4,800.

Estimated Time per Response: The participant survey will take approximately 15 minutes to complete. PHA staff implementation interviews and the staff cost interviews (to administer the staff questionnaire) will take approximately 90 minutes each to complete. The cost study checklist to be completed by PHA staff will take approximately 6 minutes to complete.

Frequency of Response: The survey, cost study checklist, PHA staff implementation interviews, and PHA staff cost interviews will each be collected once.

Estimated Total Annual Burden Hours: The total annual burden for this information collection is 84.25 hrs.

Estimated Total Annual Cost: The total annual cost for this information collection is $19,973.96. The average hourly wage of study participants is estimated from state minimum wages for the 10 states where the participating housing agencies are located ($10.72). The assumed hourly wage rate for PHA staff is based on the May 2023 employment and wages from the Occupational Employment Statistics survey from the Bureau of Labor Statistics (*http://www.bls.gov/oes/current/oes_stru.htm*). The hourly rate used for PHA program Director/Managers is $48.77, is equivalent to Social/Community Service Manager (Local Government) under SOC code 11–9151. The hourly rate used for PHA Housing Specialists is $28.50, is equivalent to the Community and Social Service Specialist (Local Government) under SOC code 21–1099. To estimate the cost burden for the Cost Study Data collection (interviews and cost study checklist), we assume 2 managers and 2 specialists will be interviewed, for an average hourly rate of $38.64.

Respondent	Occupation	SOC code	Median hourly wage rate	Average (median) hourly wage rate
Study Participant	Various (assume state minimum wage)	NA	NA	$10.72
PHA Director/Manager	Social/Community Service Manager (Local Government).	11–9151	$48.77	48.77
PHA Housing Specialist	Community and Social Service Specialist (Local Government).	21–1099	28.50	28.50

Source: Occupational Employment Statistics, accessed online May 2023, at *http://www.bls.gov/oes/current/oes_stru.htm.*

Respondent's Obligation: Voluntary.

Legal Authority: The data collection is conducted under title 12, United States Code, section 1701z and Section 3507 of the Paperwork Reduction Act of 1995, 44, U.S.C., Chapter 35.

Information Collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
30-Month Survey of Study Participants	4,800	1	1	0.25	1,200	$10.72	$12,864
PHA Director/Manager Implementation Interview	40	1	1	1.5	60	48.77	2,926
PHA Housing Specialist Implementation Interview	40	1	40	1.5	60	28.50	1,710
PHA Staff Cost Study Interview	40	1	40	1.5	60	38.64	2,318.40
PHA Staff Cost Study Checklist	40	1	40	.1	4	38.64	154.56
Total	5,000				1,384		19,973.96

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected, and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comments in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

Todd M. Richardson,

General Deputy Assistant Secretary for Policy Development and Research.

[FR Doc. 2025–00095 Filed 1–6–25; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX25LB00TZ80100; OMB Control Number 1028–0079]

Agency Information Collection Activities; North American Breeding Bird Survey

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the U.S. Geological Survey (USGS) is proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before March 10, 2025.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to U.S. Geological Survey, Information Collections Officer, 12201 Sunrise Valley Drive, MS 159, Reston, VA 20192; or by email to *gs-info_collections@usgs.gov.* Please reference OMB Control Number 1028–0079 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact David Ziolkowski by email at *dziolkowski@usgs.gov,* or by telephone at 301–497–5753. 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: In accordance with the PRA, (44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How the agency might minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. 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 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 can ask us in your comment to withhold your PII from public review, we cannot guarantee that we will be able to do so.

Abstract: Respondents supply the USGS with bird count data for more than 600 North American bird species. These data and the analyzed relative abundance and population trend estimates derived from them will be made available via the internet and through special publications, which are used by government agencies, industry, education programs, and the general public. We will protect information from respondents considered proprietary under the Freedom of Information Act (5 U.S.C. 552), its implementing regulations (43 CFR part 2), and in accordance with ''Data and information to be made available to the public or for limited inspection,'' (30 CFR 250.197). Responses are voluntary. No questions of a ''sensitive'' nature are asked.

Title of Collection: North American Breeding Bird Survey.

OMB Control Number: 1028–0079.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Individuals.

Total Estimated Number of Annual Respondents: 1,650.

Total Estimated Number of Annual Responses: 2,600.

Estimated Completion Time per Response: 11 hours on average.

Total Estimated Number of Annual Burden Hours: 28,600.

Respondent's Obligation: Voluntary.

Frequency of Collection: Annually.

Total Estimated Annual Nonhour Burden Cost: $174,200. (Mileage costs average $67 per response; based on an approximate 100-mile round trip made for data collection per response and using the U.S. GSA 2024 privately owned vehicle mileage reimbursement rate of $0.67 per mile.)

An agency may not conduct or sponsor, nor is a person is required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the PRA (44 U.S.C. 3501 *et seq.*).

David Ziolkowski,

BBS Program Manager, Eastern Ecological Science Center.

[FR Doc. 2025–00098 Filed 1–6–25; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[PO4820000251]

Notice of Availability of the Record of Decision and Approved Resource Management Plan for the Rock Springs Field Office, Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: The Bureau of Land Management (BLM) announces the availability of the Record of Decision (ROD) for the Approved Resource Management Plan (RMP) Amendment for the Rock Springs Field Office located in Rock Springs, Wyoming. The BLM Principal Deputy Director signed the ROD on December 20, 2024, which constitutes the decision of the BLM and makes the Approved RMP effective immediately.

DATES: The BLM Principal Deputy Director signed the ROD/Approved RMP Amendment on December 20, 2024.

ADDRESSES: The ROD/Approved RMP is available online at the RMP ePlanning website: *https://eplanning.blm.gov/eplanning-ui/project/13853/510*. Printed copies of the ROD/Approved RMP are available for public inspection at the Rock Springs Field Office (RSFO) or can be provided upon request by contacting Kimberlee Foster, Field Manager, telephone (307) 352–0201; or at the address BLM Rock Springs Field Office, 280 Highway 191 North, Rock Springs, WY 82901; email *kfoster@blm.gov*.

A copy of the Protest Resolution Report is available at: *https://www.blm.gov/programs/planning-and-nepa/public-participation/protest-resolution-reports.*

FOR FURTHER INFORMATION CONTACT: Kimberlee Foster, Field Manager, telephone 307–352–0201; address 280 Hwy. 191 N, Rock Springs, WY 82901; email *BLM_WY_RockSpringsRMP@blm.gov*. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting the individual listed above. 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 planning area is located in portions of Lincoln, Sweetwater, Uinta, Sublette, and Fremont counties in southwestern Wyoming, and encompasses approximately 3.6 million acres of public land.

Resources on lands administered by the BLM within the planning area are currently managed under the Green River RMP (1997) and Jack Morrow Hills Coordinated Activity Plan (CAP) (2006), as amended. The purpose of the Rock Springs RMP revision is to provide an updated, comprehensive, and environmentally adequate framework for managing and allocating uses of public lands and resources administered by the BLM in the RSFO. The Rock Springs RMP EIS evaluated a variety of resource conflicts and considered uses such as energy and minerals development, renewable energy, transmission infrastructure, lands and realty actions, and livestock grazing/rangeland management, as well as resource protections for cultural and historic resources and wildlife habitat.

The BLM published a notice of availability for the Draft EIS and RMP in the **Federal Register** on August 17, 2023, which initiated a 152-day comment period (88 FR 56654). During the public comment period, the BLM received more than 35,000 unique written submissions containing approximately 4000 substantive comments. The Draft EIS comments helped the BLM refine the Final EIS and guided the development of the Proposed RMP.

The BLM provided the Proposed RMP for public protest on August 23, 2024 (89 FR 68187), for a 30-day protest period, and received 27 letters that contained valid protests. The BLM Assistant Director for Resources and Planning resolved all protests. Responses to protest issues were compiled and documented in a Protest Resolution Report (see **ADDRESSES**). No changes were made to the Approved RMP as a result of protest resolution.

The BLM provided the Proposed RMP to the Governor of Wyoming for a 60-day Governor's consistency review. The State Director made no changes to the Proposed RMP as a result of the Governor's review. On December 13, 2024, the Governor submitted an appeal to the BLM on the State Director's response to the Governor's consistency review. In accordance with planning regulations (1610.3–2), the BLM notified the Governor on December 20, 2024, of the reasons for the determination to reject the Governor's recommendations.

(Authority: 40 CFR 1506.6; 43 CFR 1610.5–1)

Andrew Archuleta,

BLM State Director.

[FR Doc. 2025–00079 Filed 1–6–25; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[PO #4820000251]

BLM Director's Response to the State of Alaska Governor's Appeal of the BLM Alaska State Director's Governor's Consistency Review Determination for the Central Yukon Resource Management Plan and Final Environmental Impact Statement

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of response.

SUMMARY: The Bureau of Land Management (BLM) is publishing this notice of the reasons for the BLM Director's determination to reject the Governor of Alaska's recommendations regarding the Central Yukon Proposed Resource Management Plan (RMP) and Final Environmental Impact Statement (EIS).

ADDRESSES: A copy of the Central Yukon Record of Decision and Approved RMP is available on the BLM website at: *https://eplanning.blm.gov/eplanning-ui/admin/project/35315/570*.

FOR FURTHER INFORMATION CONTACT: Heather Bernier, Division Chief for Decision Support, Planning, and National Environmental Policy Act; telephone 303–239–3635; address P.O. Box 15129, Lakewood, CO 80215; email *hbernier@blm.gov*. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting Ms. Bernier. 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 April 26, 2024, the BLM released the Central Yukon Proposed RMP and Final EIS (89 FR 32457). In accordance with the regulations at 43 CFR 1610.3–2(e), the BLM submitted the Central Yukon Proposed RMP/Final EIS to the Governor of Alaska for a 60-day Governor's Consistency Review in order for the Governor to review the Proposed RMP and identify any inconsistencies with State plans, policies, or programs. On June 25, 2024, the Governor of Alaska submitted a response for the Central Yukon Proposed RMP/Final EIS to the BLM Alaska State Director.

After careful review and consideration of the concerns raised in the Governor's Consistency Review

letter, the State Director decided not to adopt the recommendations made by the Governor. On August 13, 2024, the State Director sent a written response to the Governor describing the reasons for which the State Director believes that the Proposed RMP is consistent with State land use plans, policies, and programs to the maximum extent allowed under Federal law.

On September 13, 2024, the Governor of Alaska appealed the State Director's decision not to accept his recommendations to the BLM Director. In the Governor's appeal letter, the State of Alaska requested the BLM Director to reconsider many of the issues and recommendations raised in the Governor's Consistency Review letter. In reviewing these appeals, the regulations at 43 CFR 1610.3–2(e) state that ''[t]he Director shall accept the (consistency) recommendations of the Governor(s) if he/she determines they provide for a reasonable balance between the state's interest and the national interest.'' On November 12, 2024, prior to the State Director's approval of the Central Yukon Record of Decision and Approved Resource Management Plan, the BLM Director issued a response to the Governor detailing the reasons that the recommendations did not meet this standard. Pursuant to 43 CFR 1610.3–2, the BLM Director's response to the Governor providing the basis for the BLM Director's determination on the Governor's appeal is published verbatim below.

''This letter addresses the State of Alaska's appeal of the response provided by the Bureau of Land Management (BLM) Alaska State Director regarding your consistency review of the Central Yukon Proposed Resource Management Plan (RMP) and Final Environmental Impact Statement (EIS). The Governor's consistency review is an important part of the BLM land use planning process, and we appreciate the significant time and attention that you and your staff have committed to this effort.

The applicable regulations at 43 CFR 1610.3–2(e) provide you with the opportunity to appeal the State Director's decision to not accept the recommendations you made in your consistency review letter. These regulations also guide my review of the appeal, in which I must consider whether you have raised actual inconsistencies with State or local plans, policies, and or programs. If inconsistencies are raised, I consider whether your recommendations address the inconsistencies and provide for a reasonable balance between the national interest and the State of Alaska's interest.

In your appeal of the BLM Alaska State Director's response to your consistency review, you asserted the following nine issues that the Alaska State Director determined to be outside the scope of the Governor's consistency review:

- That significant conveyances to the State are blocked by BLM's failure to revoke Public Land Order (PLO) 5150, and subsistence impacts are the justification for this failure, which is in direct violation of Alaska National Interest Lands Conservation Act (ANILCA) section 810(c);
- That failure to lift PLO 5150 and the Alaska Native Claims Settlement Act (ANCSA) section 17(d)(1) withdrawals is a land entitlement issue and is inconsistent with approved State plans;
- That the Proposed RMP does not address the concerns or plans to address those in the Northwest Alaska Transportation Plan (NWATP);
- That the Proposed RMP is inconsistent with Federal statutes that implement the goals of the Alaska Statehood Act and protect the State's resource management responsibilities, including the Alaska Statehood Act, ANCSA, and ANILCA;
- That the North Slope Area Plan (NSAP) did not find any lands requiring management areas of critical environmental concern (ACEC);
- That the RMP fails to meet commitments in the Master Memorandum of Understanding with Alaska Department of Fish and Game;
- That the Proposed RMP is inconsistent with the Alaska Wildlife Action Plan (2015) which identifies sentinel species that were not included in the species identified by BLM in the Proposed RMP/FEIS;
- That guidance to communicate on land use planning and sustainable fish and wildlife populations should be developed in collaboration to achieve State goals and objectives, and;
- That the Proposed plan is inconsistent with the John D Dingell, Jr Conservation Management and Recreation Act (Dingell Act) with regard to hunting and fishing opportunities.

Upon review, I find that these abovementioned issues do not identify an inconsistency with State or local plans, policies, or programs. Therefore, they do not fall within the scope of 43 CFR 1610.3–2(e). Even though the State Director found that these issues were out of scope, he responded to each of them to explain why. Even if they were within the scope of the Governor's Consistency Review, the Proposed RMP was not inconsistent with State plans, policies, or programs. I affirm all the State Director's responses to the abovementioned issues.

The majority of issues identified in your appeal relate to whether the BLM's recommendations to the Secretary regarding ANCSA section 17(d)(1) withdrawals and PLO 5150 frustrate the State's land entitlement under the Statehood Act and whether such recommendation is inconsistent with State plans, particularly the NSAP, the Dalton Highway Master Plan, and the NWATP. While the NSAP and the Dalton Highway Master Plan are discussed in general terms, neither the consistency review nor the appeal identified any provisions of those plans that are inconsistent with the recommendation in the Central Yukon Proposed RMP to retain PLO 5150. The consistency review letter and appeal do provide more detail about the NWATP, but do not explain how the Governor's recommendation provides a reasonable balance between the State's interest and the national interest.

Even if the inconsistencies identified with the NWATP were within the scope of the Governor's consistency review, the Central Yukon Proposed RMP is not inconsistent with that plan. First, the Governor's consistency review letter argued that retention of PLO 5150 is inconsistent with the NWATP because the Central Yukon Proposed RMP would limit the ability of the State to develop good quality road material sources across the planning area. However, as explained in the State Director's Response, PLO 5150 and ANCSA section 17(d)(1) withdrawals do not restrict BLM's ability to grant right-of-way (ROW) or conduct material sales within the planning area.

In response, your appeal letter argues instead that the location of ROW exclusion or avoidance areas would have significant impacts on the State's ability to ensure regional connectivity and that the BLM give attention on the location of ROW exclusion or avoidance areas in relation to State identified areas of potential resource value. The letter, however, does not identify any examples where a ROW exclusion or avoidance area would limit the State's access to ''areas of potential resource value'' and the NWATP does not identify any such areas. Therefore, the Governor has not identified any inconsistencies between the NWATP and the Central Yukon Proposed RMP.

Further, as explained in the State Director's response to your appeal, the Proposed RMP/FEIS recommends a partial revocation of the ANCSA section 17(d)(1) withdrawals within the Central

Yukon planning area for the limited purpose of allowing Alaska Native Vietnam-era veterans to select allotments under section 1119 of the Dingell Act, but to stay otherwise withdrawn. The Central Yukon planning effort determined that it is in the public interest to continue the protection afforded by the ANCSA section 17(d)(1) withdrawals for the lands within the planning area, particularly with regards to ensuring subsistence access and maintenance of subsistence resources. Revocation of the PLO 5150 corridor and the overlying ANCSA section 17(d)(1) withdrawals would result in loss of access for the rural subsistence users to Federal public lands on both sides of the Dalton Highway.

As described in the Central Yukon Proposed RMP/FEIS, the ANCSA section 17(d)(1) withdrawals and PLO 5150 are still fulfilling the purposes for which each were created. While the BLM understands the importance that the State places on receiving lands within the 5150 corridor, the BLM's recommendations in the Central Yukon planning effort must also consider the need to protect the public interest of the land. Overall, the Proposed RMP/FEIS analysis shows that revocation of the PLO 5150 and ANCSA section 17(d)(1) withdrawals would have significant environmental impacts and impacts to the public interest, and for those reasons the BLM does not recommend revocation of either at this time. The BLM is ready to convey the remaining acres of entitlement as soon as the State requests the conveyance of lands from its selections. Therefore, I affirm the State Director's determination in regard to the revocation of PLO 5150 and the ANCSA section 17(d)(1) withdrawals and do not accept the Governor's recommendation because it does not provide a reasonable balance between the State's interest and the national interest.

Your appeal identified an issue within the scope of the Governor's Consistency Review where you believed that the Proposed RMP is inconsistent with State land use plans, programs, and policies, to which the State Director also provided an in-depth response. Specifically, you allege that the Central Yukon RMP is inconsistent with the NSAP emphasis on access to lands for fish and game and infrastructure development, and that the State asserts that the proposed backcountry conservation area, extensive recreation management area, special recreation management area assignments conflict with the transportation corridor for the Dalton Highway. It is your recommendation on this specific issue that the BLM should analyze how the plans relate to BLM's management and address the State's access interests. As explained in the State Director's response letter, the BLM did review the NSAP in the Central Yukon RMP planning process, found no inconsistencies, and added a reference to the NSAP in the approved RMP, appendix C, Relationship to BLM Policies, Plans, and Programs.

Under all alternatives, the proposed management decisions would be subject to valid existing rights. Similarly, this planning effort is not intended to provide any evidence bearing on or addressing the validity of any Revised Statute 2477 (RS 2477) assertions and does not adjudicate, analyze, or otherwise determine the validity of claimed ROWs. RS 2477 rights are determined though a separate process outside of the land use planning process. In order to remove any potential confusion on the adjudication status of the claimed RS 2477 routes, the maps no longer label any routes as RS 2477 route. Instead, the maps will simply refer to existing routes as trail or road. The BLM will adjust its management as necessary if the Federal courts adjudicate the existence or scope of any RS 2477 ROWs. Because the BLM did review the NSAP as part of the planning process and concluded that it is not inconsistent with the Central Yukon Proposed RMP, I have determined that the Governor's recommendation to reopen the analysis to further analyze the interaction between the State and Federal plans does not strike a reasonable balance between the State's interest and the national interest.

The BLM has prepared the Central Yukon Proposed RMP/FEIS in accordance with all applicable Federal laws, regulations, and policies. The BLM did carefully review and consider applicable State, local, and other Federal agency plans, policies, and programs in the development of the Central Yukon Proposed RMP/FEIS. The BLM is consistent, to the extent practicable, with these plans as per the provisions of the Federal Land Policy and Management Act (FLPMA) and the planning regulations at 43 CFR 1610–3–2.

In conclusion, I find that the State Director properly consider all applicable State and local plans, policies, and programs in the Central Yukon planning effort, and when he responded to the Governor's consistency review. I have determined that, for most issues, you either did not raise any inconsistencies or recommendations to resolve any inconsistencies. For the issue in which you did identify an alleged inconsistency and provided a recommendation, I found it did not present a reasonable balance between the State's interest and the national interest.

Based on the foregoing, I find that the recommendations provided in your appeal letter do not meet the standard identified above for granting an appeal in accordance with 43 CFR 1610.3–2(e). Therefore, I affirm the Alaska State Director's response to your finding of inconsistency and respectfully deny your appeal. The reasons outlined above for my decision on your appeal will also be published in the **Federal Register** pursuant to the applicable BLM regulations.

Further, please note that the BLM gave due consideration to the State's concerns raised in the protest letter dated May 28, 2024. For a detailed response to these issues, many of which were raised in your consistency review letter, I refer you to the Director's Protest Resolution Report which can be found at this link: (*https://www.blm.gov/programs/planning-and-nepa/public-participation/protest-resolution-reports*).

The BLM and the State of Alaska have a long history of working cooperatively on the development of resource management plans. I appreciate the resources and input that you and your staff have put into the process of developing the Proposed RMP for the Central Yukon planning area. As mentioned, I believe this plan balances responsible development with the protection and conservation of subsistence use, important habitats for fish and wildlife, and other special values. I look forward to our continued coordination as our teams work together to implement this plan. An identical response has been sent to the cosigners of your letter.''

(*Authority:* 43 CFR 1610.3–2(e))

Nada Wolff Culver,

Principal Deputy Director.

[FR Doc. 2025–00072 Filed 1–6–25; 8:45 am]

BILLING CODE 4331–10–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[PO #4820000251; ORORI06205169; ORORI–069823]

Public Land Order No. 7957; Withdrawal of Public Land for the Protection of Three Recreation Sites; Oregon

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: Subject to valid existing rights, this order withdraws 103.92 acres of Bureau of Land Management (BLM)-administered public lands in Douglas County, Oregon from location and entry under the United States mining laws, but not from leasing under the mineral and geothermal leasing laws, for a period of 20 years to protect the unique recreational values at three public recreation sites. This Public Land Order (PLO) would also withdraw an additional 38.5 acres of non-Federal lands and an additional 21.20 acres of non-Federal subsurface mineral interests in the same manner described in the PLO, should the United States acquire such lands or interests in land in the future.

DATES: This PLO takes effect on January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Luke Poff, Realty Specialist, BLM Oregon/Washington State Office, at 503–808–6001, by email at *lpoff@blm.gov,* or at the address noted above. 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 purpose of the withdrawal is to protect the unique recreational values, as well as current and future site improvements, at the BLM's Island Creek Recreation Area, Iron Mountain Recreation Area, and Olalla-Thompson Day Use Recreation Area. Improvements within these site locations range from gravel parking areas and basic signage at the less developed areas, to paved parking, restrooms, picnic tables, grills, fire rings, and trails at the Island Creek Recreation Area.

Order

By virtue of the authority vested in the Secretary of the Interior by section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714, it is ordered as follows:

1. Subject to valid existing rights, the following described public lands are hereby withdrawn from location and entry under the United States mining laws, but not from leasing under the mineral and geothermal leasing laws, to protect three Bureau of Land Management public recreation sites.

Iron Mountain Recreation Area

Willamette Meridian, Oregon

T. 31 S., R. 7 W.,
Sec. 4, NE¼SE¼, excepting that portion granted to the railroad under the Act of July 25, 1866 (14 Stat. 239).
The area described contains 36.60 acres.

Olalla-Thompson Creek Day Use Area

Willamette Meridian, Oregon

T. 30 S., R. 7 W.,
Sec. 5, SW¼NE¼SW¼, SE¼NW¼SW¼, and N½NE¼SW¼SW¼.
The area described contains 25.00 acres.

Island Creek Recreation Area

Willamette Meridian, Oregon

T. 31 S., R. 7 W.,
Sec. 1, lot 5, excepting that portion of lot 5 granted to the railroad under the Act of July 25, 1866 (14 Stat. 239).
The area described contains 42.32 acres.

2. The following described public lands with non-Federal mineral interests, if mineral rights are acquired by United States, will be subject to the terms and conditions of this withdrawal as described in paragraph 1:

Island Creek Recreation Area

Willamette Meridian, Oregon

T. 30 S., R. 7 W.,
Sec. 36, those portions of the S½SW¼SE¼SW¼ and the S½SE¼SE¼SW¼ lying between the ordinary high-water mark of the easterly bank of Cow Creek and the southerly boundary of the Oregon & California Railroad Grant patent dated May 6, 1896.
T. 31 S., R. 7 W.,
Sec. 1, that portion of the NW¼NW¼ lying between the ordinary high-water mark of the southwesterly bank of Cow Creek and the southerly boundary of the Oregon & California Railroad Grant patent dated May 6, 1896.
The areas described aggregate 21.20 acres.

3. The following described non-Federal lands, if acquired by the United States, will be subject to the terms and conditions of this withdrawal as described in paragraph 1:

Island Creek Special Recreation Site

Willamette Meridian, Oregon

T. 30 S., R. 7 W.,
Sec. 36, S½SW¼SW¼SW¼, S½SE¼SW¼SW¼, S½SW¼SE¼SW¼, and S½SE¼SE¼SW¼, excepting those portions of the S½SW¼SE¼SW¼ and the S½SE¼SE¼SW¼ lying between the ordinary high-water mark of the easterly bank of Cow Creek and the southerly boundary of the Oregon & California Railroad Grant patent dated May 6, 1896.
T. 31 S., R. 7 W.,
Sec. 1, that portion of lot 5 granted to the railroad under the Act of July 25, 1866 (14 Stat. 239), and NW¼NW¼, excepting that portion of the NW¼NW¼ lying between the ordinary high-water mark of the southwesterly bank of Cow Creek and the southerly boundary of the Oregon & California Railroad Grant patent dated May 6, 1896.
The areas described aggregate 38.50 acres.
The total areas described, including public and non-Federal lands, aggregate 163.62 acres.

4. The withdrawal made by this order does not alter the applicability of those public land laws governing the use of the lands under lease, license, or permit, or governing the disposal of their mineral or vegetative resources other than under the mining laws.

5. This withdrawal will expire 20 years from the effective date of this order, unless, as a result of a review conducted before the expiration date pursuant to section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f), the Secretary determines that the withdrawal shall be extended.

(Authority: 43 U.S.C. 1714)

Robert T. Anderson,

Solicitor.

[FR Doc. 2025–00006 Filed 1–6–25; 8:45 am]

BILLING CODE 4331–24–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[PO #4820000251; NM–052394; NM–052395]

Public Land Order No. 7955; Partial Revocation of Withdrawals Created by Secretary Orders Dated December 10 and 22, 1928, for the Avalon Reservoir Carlsbad Project; New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This Public Land Order (Order) partially revokes two withdrawals created by Secretary's orders dated December 10 and 22, 1928, issued pursuant to the Reclamation Act of June 17, 1902, section 3, to support the Bureau of Reclamation's (BOR) Avalon Reservoir Carlsbad Project. The BOR has determined that 335.25 acres of withdrawn lands are no longer needed for reclamation purposes and has

requested that the withdrawals be partially revoked. This Order opens the lands to appropriation under the public land laws, subject to valid existing rights.

DATES: This Order takes effect on January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Tessa Telles, BLM, Carlsbad Field Office, at (575) 234–5980 or by email *ttelles@blm.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or Tele Braille) 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 BOR has requested a partial withdrawal revocation of 335.25 acres of land originally withdrawn in support of the Avalon Reservoir Carlsbad Project created by two Secretary's orders dated December 10 and 22, 1928, issued pursuant to the Reclamation Act of June 17, 1902, section 3. The BOR has determined that the lands are no longer needed for reclamation purposes. The revocation of the withdrawal will open the lands to appropriation and allow the lands to be conveyed out of Federal ownership in a proposed land sale. Any lands not conveyed will be restored to the administration of the Bureau of Land Management.

Order

By virtue of the authority vested in the Secretary of the Interior by section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714, it is ordered as follows:

1. The withdrawals created by Secretary Orders dated December 10 and 22, 1928, which withdrew public lands for use by the Bureau of Reclamation for the Avalon Reservoir Carlsbad Project, are hereby partially revoked as to the following described lands:

New Mexico Principal Meridian

T. 21 S., R. 26 E.,
Sec. 14, lot 4;
Sec. 23, lots 1, 4, 5, 7, 8, 9, 12, and 13.

The area described contains 335.25 acres.

2. At 8 a.m. Mountain Time (MT) on January 7, 2025, the lands described above will open to the operation of the public land laws, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law. All valid applications received at or prior to 8 a.m. MT on January 7, 2025, shall be considered as simultaneously filed at that time. Those received thereafter shall be considered in the order of filing. Applications to appropriate any of the lands referenced in this Order received prior to the date and time stated above shall be rejected. The lands will remain closed to location and entry under the United States mining laws until such time as the lands are conveyed out of Federal ownership or an opening order is issued pursuant to 43 CFR 2091.6.

(Authority: 43 U.S.C. 1714)

Robert T. Anderson,

Solicitor.

[FR Doc. 2025–00003 Filed 1–6–25; 8:45 am]

BILLING CODE 4331–23–P

DEPARTMENT OF THE INTERIOR

National Park Service

[PPSESEROC3, PPMPSAS1Y.YP0000; NPS–SERO–CHAT, EVER, GUIS, JELA, LIRI, VIIS–DTS# NPS0035785]

Assessment of Eligible and Ineligible Lands for Consideration as Wilderness Areas, Chattahoochee River National Recreation Area, Everglades National Park, Gulf Islands National Seashore, Jean Lafitte National Historical Park and Preserve, Little River Canyon National Preserve, Virgin Islands National Park

AGENCY: National Park Service, Interior.

ACTION: Notice of intent.

SUMMARY: Pursuant to the Wilderness Act of 1964, and in accordance with National Park Service (NPS) Management Policies 2006, the NPS intends to evaluate all previously unassessed lands within the following parks for their eligibility for inclusion in the national wilderness preservation system: Chattahoochee River National Recreation Area, Everglades National Park, Gulf Islands National Seashore, Jean Lafitte National Historical Park and Preserve, Little River Canyon National Preserve, and Virgin Islands National Park.

DATES: Each of the listed parks will begin its wilderness eligibility assessment on January 7, 2025. All assessments are expected to be completed by January 7, 2026.

ADDRESSES: Interested individuals, organizations, and agencies are encouraged to provide written information that may assist the NPS in identifying lands eligible or ineligible for designation as wilderness. Suggestions and requests for further information should be directed to: National Park Service, Department of the Interior Region 2—South Atlantic Gulf, 100 Alabama St. SW, Atlanta, GA 30303.

FOR FURTHER INFORMATION CONTACT: PJ Walker, Regional Wilderness Coordinator, by phone at 404–507–5709, via email at *PJ_Walker@nps.gov.*

SUPPLEMENTARY INFORMATION: In furtherance of the Wilderness Act of 1964 (16 U.S.C. 1131 *et seq.*), NPS Management Policies 2006 section 6.2.1 provides that all lands administered by the NPS, including new units and additions to existing units since 1964, will be evaluated for their eligibility for inclusion in the national wilderness preservation system. Accordingly, the NPS intends to evaluate all previously unassessed lands within the following parks for wilderness eligibility: Chattahoochee River National Recreation Area (all lands), Everglades National Park (three small, noncontiguous areas not previously assessed), Gulf Islands National Seashore (Cat Island Unit), Jean Lafitte National Historical Park and Preserve (Barataria Preserve Unit), Little River Canyon National Preserve (all lands), and Virgin Islands National Park.

For areas determined to be ineligible for wilderness designation, the wilderness preservation provisions in the NPS Management Policies 2006 would not apply (NPS Management Policies 2006 section 6.2.1.3). However, ineligible lands will continue to be managed in accordance with the NPS Organic Act and all other laws, Executive orders, regulations, and policies applicable to units of the national park system.

Lands and waters found to possess the characteristics and values of wilderness, as defined in the Wilderness Act and determined eligible pursuant to the wilderness eligibility assessment, will be formally studied to develop the recommendation to Congress for wilderness designation (NPS Management Policies 2006 section 6.2.2). The wilderness study will include the appropriate level of analyses under the National Environmental Policy Act and the National Historic Preservation Act. Congress alone can designate wilderness areas.

Determinations of eligibility and subsequent future actions will be

announced in the **Federal Register** upon completion of these assessments.

Mark A. Foust,

Regional Director, Interior Region 2—South Atlantic-Gulf.

[FR Doc. 2025–00114 Filed 1–6–25; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–722–725 and 731–TA–1690–1693 (Final)]

Crystalline Silicon Photovoltaic Products (Solar Panels) From Cambodia, Malaysia, Thailand, and Vietnam; Scheduling of the Final Phase of Countervailing Duty and Antidumping Duty Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of the final phase of antidumping and countervailing duty investigation Nos. 701–TA–722–725 and 731–TA–1690–1693 (Final) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of crystalline silicon photovoltaic products (solar panels) from Cambodia, Malaysia, Thailand, and Vietnam, provided for in statistical reporting numbers 8541.42.0010 and 8541.43.0010 of the Harmonized Tariff Schedule of the United States. Crystalline silicon photovoltaic cells, whether or not assemabled into modules, may also be imported under subheadings 8501.71, 8501.72, and 8501.80 and statistical reporting number 8507.20.8010, preliminarily determined by the Department of Commerce (''Commerce'') to be subsidized and sold at less-than-fair-value.

DATES: December 4, 2024.

FOR FURTHER INFORMATION CONTACT: Julie Duffy ((202) 708–2579), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Scope.—For purposes of these investigations, Commerce has defined the subject merchandise as ''The merchandise covered by these investigations is crystalline silicon photovoltaic cells, and modules, laminates, and panels, consisting of crystalline silicon photovoltaic cells, whether or not partially or fully assembled into other products, including, but not limited to, modules, laminates, panels and building integrated materials.

These investigations cover crystalline silicon photovoltaic cells of thickness equal to or greater than 20 micrometers, having a p/n junction formed by any means, whether or not the cell has undergone other processing, including, but not limited to, cleaning, etching, coating, and/or addition of materials (including, but not limited to, metallization and conductor patterns) to collect and forward the electricity that is generated by the cell.

Merchandise under consideration may be described at the time of importation as parts for final finished products that are assembled after importation, including, but not limited to, modules, laminates, panels, buildingintegrated modules, building-integrated panels, or other finished goods kits. Such parts that otherwise meet the definition of merchandise under consideration are included in the scope of the investigations.

Excluded from the scope of the investigations are thin film photovoltaic products produced from amorphous silicon (a-Si), cadmium telluride (CdTe), or copper indium gallium selenide (CIGS). Also excluded from the scope of the investigations are crystalline silicon photovoltaic cells, not exceeding 10,000 mm^2 in surface area, that are permanently integrated into a consumer good whose function is other than power generation and that consumes the electricity generated by the integrated crystalline silicon photovoltaic cell. Where more than one cell is permanently integrated into a consumer good, the surface area for purposes of this exclusion shall be the total combined surface area of all cells that are integrated into the consumer good.

Additionally, excluded from the scope of the investigations are panels with surface area from 3,450 mm^2 to 33,782 mm^2 with one black wire and one red wire (each of type 22 AWG or 24 AWG not more than 206 mm in length when measured from panel extrusion), and not exceeding 2.9 volts, 1.1 amps, and 3.19 watts. For the purposes of this exclusion, no panel shall contain an internal battery or external computer peripheral ports.

Also excluded from the scope of the investigations are:

1. Off grid CSPV panels in rigid form with a glass cover, with the following characteristics: (A) a total power output of 100 watts or less per panel; (B) a maximum surface area of 8,000 cm^2 per panel; (C) do not include a built-in inverter; (D) must include a permanently connected wire that terminates in either an 8 mm male barrel connector, or a two-port rectangular connector with two pins in square housings of different colors; (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell; and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features, and foam for transport); and

2. Off grid CSPV panels without a glass cover, with the following characteristics: (A) a total power output of 100 watts or less per panel; (B) a maximum surface area of 8,000 cm^2 per panel; (C) do not include a built-in inverter; (D) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell; and (E) each panel is (1) permanently integrated into a consumer good; (2) encased in a laminated material without stitching, or (3) has all of the following characteristics: (i) the panel is encased in sewn fabric with visible stitching, (ii) includes a mesh zippered storage pocket, and (iii) includes a permanently attached wire that terminates in a female USB–A connector.

In addition, the following CSPV panels are excluded from the scope of the investigations: off-grid CSPV panels in rigid form with a glass cover, with each of the following physical characteristics, whether or not assembled into a fully completed off-grid hydropanel whose function is conversion of water vapor into liquid water: (A) a total power output of no more than 80 watts per panel; (B) a surface area of less than 5,000 square centimeters (cm^2) per panel; (C) do not include a built-in inverter; (D) do not have a frame around the edges of the panel; (E) include a clear glass back panel; and (F) must include a permanently connected wire that

terminates in a twoport rectangular connector.

Additionally excluded from the scope of these investigations are off-grid small portable crystalline silicon photovoltaic panels, with or without a glass cover, with the following characteristics: (1) a total power output of 200 watts or less per panel; (2) a maximum surface area of 16,000 cm^2 per panel; (3) no built-in inverter; (4) an integrated handle or a handle attached to the package for ease of carry; (5) one or more integrated kickstands for easy installation or angle adjustment; and (6) a wire of not less than 3 meters either permanently connected or attached to the package that terminates in an 8 mm diameter male barrel connector.

Also excluded from the scope of these investigations are off-grid crystalline silicon photovoltaic panels in rigid form with a glass cover, with each of the following physical characteristics, whether or not assembled into a fully completed off-grid hydropanel whose function is conversion of water vapor into liquid water: (A) a total power output of no more than 180 watts per panel at 155 degrees Celsius; (B) a surface area of less than 16,000 square centimeters (cm^2) per panel; (C) include a keep-out area of approximately 1,200 cm^2 around the edges of the panel that does not contain solar cells; (D) do not include a built-in inverter; (E) do not have a frame around the edges of the panel; (F) include a clear glass back panel; (G) must include a permanently connected wire that terminates in a two-port rounded rectangular, sealed connector; (H) include a thermistor installed into the permanently connected wire before the twoport connector; and (I) include exposed positive and negative terminals at opposite ends of the panel, not enclosed in a junction box.

Further excluded from the scope of the investigations are:

1. Off grid rigid CSPV panels with a glass cover, with the following characteristics: (A) a total power output of 200 watts or less per panel, (B) a maximum surface area of 10,500 cm^2 per panel, (C) do not include a built-in inverter, (D) must include a permanently connected wire that terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure, (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features); and

2. Off-grid small portable crystalline silicon photovoltaic panels, with or without a glass cover, with the following characteristics: (A) a total power output of 200 watts or less per panel, (B) a maximum surface area of 16,000 cm^2 per panel, (C) no built-in inverter, (D) an integrated handle or a handle attached to the package for ease of carry, (E) one or more integrated kickstands for easy installation or angle adjustment, and (F) a wire either permanently connected or attached to the package terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure.

Also excluded from the scope of the investigations are:

1. Off grid rigid CSPV panels with a glass cover, with the following characteristics: (A) a total power output of 200 watts or less per panel, (B) a maximum surface area of 10,500 cm^2 per panel, (C) do not include a built-in inverter, (D) must include a permanently connected wire that terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure, (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features); and

2. Small off-grid panels with glass cover, with the following characteristics: (A) surface area from 3,450 mm^2 to 33,782 mm^2, (B) with one black wire and one red wire (each of type 22AWG or 28 AWG not more than 350 mm in length when measured from panel extrusion), (C) not exceeding 10 volts, (D) not exceeding 1.1 amps, (E) not exceeding 6 watts, and (F) for the purposes of this exclusion, no panel shall contain an internal battery or external computer peripheral ports.

Additionally excluded from the scope of the investigations are:

1. Off grid rigid CSPV panels with a glass cover, with the following characteristics: (A) a total power output of 175 watts or less per panel, (B) a maximum surface area of 9,000 cm^2 per panel, (C) do not include a built-in inverter, (D) must include a permanently connected wire that terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure; (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features); and

2. Off grid CSPV panels without a glass cover, with the following characteristics, (A) a total power output of 220 watts or less per panel, (B) a maximum surface area of 16,000 cm^2 per panel, (C) do not include a built-in inverter, (D) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (E) each panel is encased in a laminated material without stitching.

Also excluded from the scope of these investigations are off-grid CSPV panels in rigid form, with or without a glass cover, permanently attached to an aluminum extrusion that is an integral component of an automation device that controls natural light, whether or not assembled into a fully completed automation device that controls natural light, with the following characteristics:

1. a total power output of 20 watts or less per panel;

2. a maximum surface area of 1,000 cm^2 per panel;

3. does not include a built-in inverter for powering third party devices.

Modules, laminates, and panels produced in a third-country from cells produced in a subject country are covered by the investigations; however, modules, laminates, and panels produced in a subject country from cells produced in a third-country are not covered by the investigations.

Also excluded from the scope of these investigations are all products covered by the scope of the antidumping and countervailing duty orders on *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Duty Order,* 77 FR 73018 (December 7, 2012); *and Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Countervailing Duty Order,* 77 FR 73017 (December 7, 2012).

Merchandise covered by the investigations is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 8541.42.0010 and 8541.43.0010. Imports of the subject

merchandise may enter under HTSUS subheadings 8501.71.0000, 8501.72.1000, 8501.72.2000, 8501.72.3000, 8501.72.9000, 8501.80.1000, 8501.80.2000, 8501.80.3000, 8501.80.9000, 8507.20.8010, 8507.20.8031, 8507.20.8041, 8507.20.8061, and 8507.20.8091. These HTSUS subheadings are provided for convenience and customs purposes; the written description of the scope of the investigations is dispositive.

Background.—The final phase of these investigations is being scheduled pursuant to sections 705(b) and 731(b) of the Tariff Act of 1930 (19 U.S.C. 1671d(b) and 1673d(b)), as a result of affirmative preliminary determinations by Commerce that certain benefits which constitute subsidies within the meaning of § 703 of the Act (19 U.S.C. 1671b) are being provided to manufacturers, producers, or exporters in Cambodia, Malaysia, Thailand, and Vietnam of crystalline silicon photovoltaic products (solar panels), and that such products are being sold in the United States at less than fair value within the meaning of § 733 of the Act (19 U.S.C. 1673b). The investigations were requested in petitions filed on on April 24, 2024, by the American Alliance for Solar Manufacturing Trade Committee.

For further information concerning the conduct of this phase of the investigations, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Participation in the investigations and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the final phase of these investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11 of the Commission's rules, no later than 21 days prior to the hearing date specified in this notice. A party that filed a notice of appearance during the preliminary phase of the investigations need not file an additional notice of appearance during this final phase. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

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.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in the final phase of these investigations available to authorized applicants under the APO issued in the investigations, provided that the application is made no later than 21 days prior to the hearing date specified in this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the investigations. A party granted access to BPI in the preliminary phase of the investigations need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the final phase of these investigations will be placed in the nonpublic record on April 1, 2025, and a public version will be issued thereafter, pursuant to § 207.22 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with the final phase of these investigations beginning at 9:30 a.m. on Tuesday, April 15, 2025. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before Wednesday, April 9, 2025. Any requests to appear as a witness via videoconference must be included with your request to appear. Requests to appear via videoconference must include a statement explaining why the witness cannot appear in person; the Chairman, or other person designated to conduct the investigation, may in their discretion for good cause shown, grant such a request. Requests to appear as remote witness due to illness or a positive COVID–19 test result may be submitted by 3pm the business day prior to the hearing. Further information about participation in the hearing will be posted on the Commission's website at *https://www.usitc.gov/calendarpad/calendar.html.*

A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference, if deemed necessary, to be held at 9:30 a.m. on Friday, April 11, 2025. Parties shall file and serve written testimony and presentation slides in connection with their presentation at the hearing by no later than noon on Monday, April 14, 2025. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party who is an interested party shall submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of § 207.23 of the Commission's rules; the deadline for filing is April 8, 2025. Parties shall also file written testimony in connection with their presentation at the hearing, and posthearing briefs, which must conform with the provisions of § 207.25 of the Commission's rules. The deadline for filing posthearing briefs is April 22, 2025. In addition, any person who has not entered an appearance as a party to the investigations may submit a written statement of information pertinent to the subject of the investigations, including statements of support or opposition to the petition, on or before April 22, 2025. On May 13, 2025, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before May 15, 2025, but such final comments must not contain new factual information and must otherwise comply with § 207.30 of the Commission's rules. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

Additional written submissions to the Commission, including requests pursuant to § 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with §§ 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the

investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.21 of the Commission's rules.

By order of the Commission.

Issued: December 20, 2024.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2025–00001 Filed 1–6–25; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Shapewear Garments and Components Thereof, DN 3799;* 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 Spanx, LLC on December 31, 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 shapewear garments and components thereof. The complaint names as respondents: Honeylove Sculptwear, Inc. of Los Angeles, CA; Guangzhoushi Chiping Dianzi Maoyi Co. Ltd. of China; Daerwene Inc. of Boulder, CO; Guangzhoushi Cedong Shangmao Youxiangongsi of China; Bingrong Co., Ltd of China; and Dolce Vita Intimates LLC of Harrison, NJ. The complainant requests that the Commission issue a general exclusion order or, in the alternative, issue a limited exclusion order, cease and desist orders, and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, members of the public, and interested government agencies 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. 3799'') 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: December 31, 2024.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2024–31789 Filed 1–6–25; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–753 and 731–TA–1731 (Preliminary)]

Slag Pots from China; Institution of Antidumping and Countervailing Duty Investigations and Scheduling of Preliminary Phase Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigation Nos. 701–TA–753 and 731–TA–1731 (Preliminary) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of slag pots from China, provided for in subheading 7309.00.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Government of China. Unless the Department of Commerce (''Commerce'') extends the time for initiation, the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by February 14, 2025. The Commission's views must be transmitted to Commerce within five business days thereafter, or by February 24, 2025.

DATES: December 31, 2024.

FOR FURTHER INFORMATION CONTACT: Jordan Harriman (202–205–2610), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*.

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), in response to a petition filed on December 31, 2024, by WHEMCO-Steel Castings, Inc., Pittsburgh, Pennsylvania.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

Participation in the investigations and public service list.—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in §§ 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping duty and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—The Office of Investigations will hold a staff conference in connection with the preliminary phase of these investigations beginning at 9:30 a.m. on Tuesday, January 21, 2025. Requests to appear at the conference should be emailed to *preliminaryconferences@usitc.gov* (DO NOT FILE ON EDIS) on or before Thursday, January 16, 2025. Please provide an email address for each conference participant in the email. Information on conference procedures, format, and participation, including guidance for requests to appear as a witness via videoconference, will be available on the Commission's Public Calendar (Calendar (USITC) √ United States International Trade Commission). A nonparty who has testimony that may aid the Commission's deliberations may request permission to participate by submitting a short statement.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Written submissions.—As provided in §§ 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before 5:15 p.m. on January 24, 2025, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties shall file written testimony and supplementary material in connection with their presentation at the conference no later than 4:00 p.m. on January 17, 2025. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these investigations must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that any information that it submits to the Commission during these investigations may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of these or related investigations or reviews, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.12 of the Commission's rules.

By order of the Commission.

Issued: January 2, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025–00067 Filed 1–6–25; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1110–0064]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Previously Approved Collection; FBI Expungement and Sealing Form (FD–1114)

AGENCY: Criminal Justice Information Services (CJIS) Division, Federal Bureau of Investigation (FBI), Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The CJIS Division, FBI, DOJ, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until March 10, 2025.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Brian A. Cain, Management and Program Analyst, FBI, CJIS, Criminal History Information and Policy Unit, BTC–3, 1000 Custer Hollow Road, Clarksburg, WV 26306; phone: 304–625–5590 or email *bacain@fbi.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so, how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Abstract: It is essential the FBI Expungement Form (FD–1114) be utilized for the CJIS Division, to assure identity history information is collected, stored, removed and thus, disseminated in a manner to ensure accuracy, completeness, currency, integrity, and security of such information to protect individual privacy and provide maximum service to all law enforcement and governmental agencies. All of which is imposed on the FBI, CJIS Division, by 28 CFR 20.1.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a previously approved collection.

2. *The Title of the Form/Collection:* FBI Expungement and Sealing Form.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* (FD–1114); CJIS, FBI, DOJ.

4. *Affected public who will be asked or required to respond, as well as the obligation to respond:* Affected Public: State, local and tribal governments, Federal Government. The obligation to respond is required to mandatory per 28 CFR 20.37 as agencies contributing data to the NGI System are responsible for accuracy, completeness, currency, and integrity.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated number of yearly responses for the FBI Expungement and Sealing Form (FD–1114) is 147,610. The estimated time to complete the form is 3.5 minutes.

6. *An estimate of the total annual burden (in hours) associated with the collection:* The estimated annual burden hours for this collection is 8,611 hours. (147,610 responses × 3.5 minutes/60 = 8611 hours.

7. *An estimate of the total annual cost burden associated with the collection, if applicable:* N/A.

TOTAL BURDEN HOURS

Activity	Number of respondents	Frequency (annually)	Total annual responses	Time per response (min)	Total annual burden (hours)
Ex: Survey (individuals or households)	147,610	1	147,610	3.5	8,611
Unduplicated Totals	147,610		147,610		8,611

If additional information is required contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC.

Dated: December 31, 2024.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2024–31782 Filed 1–6–25; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

[OMB 1140–0108]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Previously Approved Collection; Forensic Firearm Training Request for Non-ATF Employees—ATF Form 7110.15

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until March 10, 2025.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, contact: Jodi Marsanopoli, ATF National Laboratory Center, either by mail at ATF National Laboratory Center; 6000 Ammendale Road; Ammendale, MD 20705, by email at *jodi.marsanopoli@atf.gov* or telephone at 202–527–5078.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Abstract: The Forensic Firearm Training Request for Non-ATF Students (ATF F 7110.15) will be used to obtain information from Federal, State and local, and international law enforcement personnel to register, obtain course information, and/or evaluate ATF forensic firearms investigative techniques training. Information Collection (IC) OMB 1140–0108 is being revised to include the monetized value (from $0 to $ 1,832 (rounded)), which this ICR did not include before. The number of respondents has also increased since 2021, from 75 to 150, resulting in a consequential increase in the total burden hours from 29.5 hours to 37.5 hours.

Overview of This Information Collection

1. *Type of Information Collection*: Revision of a previously approved collection.

2. *The Title of the Form/Collection*: Forensic Firearm Training Request for Non-ATF Employees.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection*: Form number: ATF Form 7110.15.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as the obligation to respond*: Affected Public: State, local and Tribal governments and Federal Government.

The obligation to respond is voluntary.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond*: An estimated 150 respondents will provide information to complete this form once annually, and it will take each respondent approximately 0.25 hours to complete their responses.

6. *An estimate of the total annual burden (in hours) associated with the collection*: The estimated annual public burden associated with this collection is 37.5 total hours, which is equal to 150 (total respondents) * 1 (# of response per respondent) * 0.25 (hours).

7. *An estimate of the total annual cost burden associated with the collection, if applicable*: $1,831.50.

TOTAL BURDEN HOURS

Activity	Number of respondents	Frequency	Total annual responses	Time per response	Total annual burden (hours)
Student Forensic Firearm Training Request Form 7110.15	150	1/annually	150	0.25 hours	37.5 hours

TOTAL BURDEN HOURS—Continued

Activity	Number of respondents	Frequency	Total annual responses	Time per response	Total annual burden (hours)
Unduplicated Totals	150	1/annually	150	0.25 hours	37.5 hours

If additional information is required contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC.

Dated: December 31, 2024.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2024–31784 Filed 1–6–25; 8:45 am]

BILLING CODE 4410–FY–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board's (NSB) Committee on Oversight (CO) hereby gives notice of the scheduling of a videoconference for the transaction of National Science Board business pursuant to the National Science Foundation Act and the Government in the Sunshine Act.

TIME AND DATE: Friday, January 10, 2025, from 1:00 p.m.–2:00 p.m. Eastern.

PLACE: The meeting will be held by videoconference through the National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314. Members of the public can observe this meeting through a YouTube livestream. The YouTube link will be available from the NSB meetings web page—*https://www.nsf.gov/nsb/meetings/index.jsp.*

STATUS: Open.

MATTERS TO BE CONSIDERED: Chair's opening remarks and approval of previous committee minutes; Presentation by NSF regarding the Merit Review Digests for FY 2022 and 2023 and Committee discussion; Update by the Chief Financial Officer; Presentation by the external auditor for the Office of the Inspector General on results of the FY 2024 Financial Statement audit; Chair's closing remarks.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is Chris Blair, *cblair@nsf.gov,* 703/292–7000.

Ann E. Bushmiller,

Senior Counsel to the National Science Board.

[FR Doc. 2025–00272 Filed 1–3–25; 4:15 pm]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 72–70, 50–373, and 50–374; NRC–2024–0205]

Constellation Energy Generation, LLC; LaSalle County Station Units 1 and 2; Independent Spent Fuel Storage Installation; Exemption

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) issued an exemption to Constellation Energy Generation, LLC, permitting LaSalle County Station (LSCS) to maintain four loaded and to load four new 68M multi-purpose canister with continuous basket shims in HI–STORM 100 Cask System at its LSCS Units 1 and 2 independent spent fuel storage installation in a storage condition where the terms, conditions, and specifications in the Certificate of Compliance No. 1014, Amendment No. 8, Revision No. 1, are not met.

DATES: The exemption was issued on December 20, 2024.

ADDRESSES: Please refer to Docket ID NRC–2024–0205 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–2024–0205. 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.* 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: Martin Ortiz Gonzalez, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3637; email: *Martin.OrtizGonzalez@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the exemption is attached.

Dated: January 2, 2025.

For the Nuclear Regulatory Commission.

Yen-Ju Chen,

Acting Chief, Storage and Transportation Licensing Branch, Division of Fuel Management, Office of Nuclear Material Safety, and Safeguards.

Attachment—Exemption

NUCLEAR REGULATORY COMMISSION

Docket Nos. 72–70, 50–373, and 50–374

Constellation Energy Generation, LLC; LaSalle County Station Units 1 and 2; Independent Spent Fuel Storage Installation

I. Background

Constellation Energy Generation, LLC (CEG), is the holder of Renewed Facility Operating Licenses Nos. NPF–11 and NPF–18, which authorize operation of the LaSalle County Station, (LSCS) Units 1 and 2 in Marseilles, Illinois, pursuant to Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR), ''Domestic Licensing of Production and Utilization Facilities.'' The licenses provide, among other things, that the facility is subject to all rules, regulations, and orders of the U.S. Nuclear Regulatory Commission (NRC) now or hereafter in effect.

Consistent with 10 CFR part 72, subpart K, ''General License for Storage of Spent Fuel at Power Reactor Sites,''

a general license is issued for the storage of spent fuel in an Independent Spent Fuel Storage Installation (ISFSI) at power reactor sites to persons authorized to possess or operate nuclear power reactors under 10 CFR part 50. CEG is authorized to operate nuclear power reactors under 10 CFR part 50 and holds a 10 CFR part 72 general license for storage of spent fuel at the LSCS ISFSI. Under the terms of the general license, CEG stores spent fuel at its LSCS ISFSI using the HI–STORM 100 Cask System in accordance with Certificate of Compliance (CoC) No. 1014, Amendment No. 8, Revision No. 1.

II. Request/Action

By a letter dated September 19, 2024 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML24263A206), CEG requested an exemption from the requirements of 10 CFR 72.212(a)(2), 72.212(b)(3), 72.212(b)(5)(i), 72.212(b)(11), and 72.214 that require LSCS to comply with the terms, conditions, and specifications of the CoC No. 1014, Amendment No. 8, Revision No. 1 (ML16041A233). If approved, CEG's exemption request would accordingly allow LSCS to maintain four loaded and to load, in the future loading campaign beginning in June 2025, four Multi-Purpose Canisters (MPCs) with an unapproved, variant basket design with continuous basket shims (CBS) (*i.e.,* MPC–68M–CBS) in the HI–STORM 100 Cask System, and thus, to maintain and load the systems in a storage condition where the terms, conditions, and specifications in the CoC No. 1014, Amendment No. 8, Revision No. 1, are not met.

CEG currently uses the HI–STORM 100 Cask System under CoC No. 1014, Amendment No. 8, Revision No. 1, for dry storage of spent nuclear fuel in MPC–68M at the LSCS ISFSI. Holtec International (Holtec), the designer and manufacturer of the HI–STORM 100 Cask System, developed a variant of the design with CBS for the MPC–68M, known as MPC–68M–CBS. Holtec performed a non-mechanistic tip-over analysis with favorable results and implemented the CBS variant design under the provisions of 10 CFR 72.48, ''Changes, tests, and experiments,'' which allows licensees to make changes to cask designs without a CoC amendment under certain conditions (listed in 10 CFR 72.48(c)). After evaluating the specific changes to the cask designs, the NRC determined that Holtec erred when it implemented the CBS variant design under 10 CFR 72.48, as this is not the type of change allowed without a CoC amendment. For this reason, the NRC issued three Severity Level IV violations to Holtec (ML24016A190).

Prior to the issuance of the violation, CEG had loaded four MPC–68M–CBS in the HI–STORM 100 Cask System, which are safely in storage at the LSCS ISFSI. CEG's future loading campaign for the LSCS ISFSI includes loading four MPC–68M–CBS in the HI–STORM 100 Cask System beginning in June 2025. While Holtec was required to submit a CoC amendment to the NRC to seek approval of the CBS variant design, such a process will not be completed in time to inform decisions for this future loading campaign. Therefore, CEG submitted this exemption request in order to allow for the continued storage of the four already loaded MPC–68–CBS, and future loading of four MPC–68M–CBS, beginning in June 2025, at the LSCS ISFSI. This exemption is limited to the use of MPC–68M–CBS in the HI–STORM 100 Cask System only for the four already loaded canisters and the specific planned loading of four new canisters beginning in June 2025.

III. Discussion

Pursuant to 10 CFR 72.7, ''Specific exemptions,'' the Commission may, upon application by any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations of 10 CFR part 72 as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

A. The Exemption Is Authorized by Law

This exemption would allow CEG to maintain four loaded and to load four MPC–68M–CBS in the future loading campaign beginning in June 2025, in the HI–STORM 100 Cask System at its LSCS ISFSI in a storage condition where the terms, conditions, and specifications in the CoC No. 1014, Amendment No. 8, Revision No. 1, are not met. CEG is requesting an exemption from the provisions in 10 CFR part 72 that require the licensee to comply with the terms, conditions, and specifications of the CoC for the approved cask model it uses. Section 72.7 allows the NRC to grant exemptions from the requirements of 10 CFR part 72. This authority to grant exemptions is consistent with the Atomic Energy Act of 1954, as amended, and is not otherwise inconsistent with NRC's regulations or other applicable laws. Additionally, no other law prohibits the activities that would be authorized by the exemption. Therefore, the NRC concludes that there is no statutory prohibition on the issuance of the requested exemption, and the NRC is authorized to grant the exemption by law.

B. The Exemption Will Not Endanger Life or Property or the Common Defense and Security

This exemption would allow CEG to maintain four loaded and to load four MPC–68M–CBS in the future loading campaign beginning in June 2025, in the HI–STORM 100 Cask System at the LSCS ISFSI in a storage condition where the terms, conditions, and specifications in the CoC No. 1014, Amendment No. 8, Revision No. 1, are not met. In support of its exemption request, CEG asserts that issuance of the exemption would not endanger life or property because the administrative controls the applicant has in place prevent a tip-over or handling event, and that the containment boundary would be maintained in such an event. CEG relies, in part, on the approach in the NRC's Safety Determination Memorandum (ML24018A085). The NRC issued this Safety Determination Memorandum to address whether, with respect to the enforcement action against Holtec regarding this violation, there was any need to take an immediate action for the cask systems that were already loaded with non-compliant basket designs. The Safety Determination Memorandum documents a risk-informed approach concluding that, during the design basis event of a non-mechanistic tip-over, the fuel in the basket in the MPC–68M–CBS remains in a subcritical condition.

CEG also provided site-specific technical information, including information explaining why the use of the approach in the NRC's Safety Determination Memorandum is appropriate for determining the safe use of the CBS variant baskets at the LSCS ISFSI. Specifically, CEG described that the analysis of the tip-over design basis event that is relied upon in the NRC's Safety Determination Memorandum, which demonstrates that the MPC confinement barrier is maintained, is documented in the updated final safety analysis report (UFSAR) for the HI–STORM 100 Cask System CoC No. 1014, Amendment 8, Revision No. 1, that is used at the LSCS site. CEG also described its administrative controls for handling of the HI–STORM 100 Cask System at the LSCS ISFSI to prevent a tip-over or handling event. Those controls include operational procedures that demonstrate the system is handled with a single failure proof device in accordance with NUREG–0554 (ML110450636), ''Single-Failure-Proof Cranes for Nuclear Power Plants, NUREG–0612, ''Control of Heavy Loads

at Nuclear Power Plants'' (ML070250180), and ANSI N14.6, ''for Radioactive Materials—Special Lifting Devices for Shipping Containers Weighing 10 000 Pounds (4500 kg) or More,'' and employing redundant drop protection features which comply with CoC No. 1014, Amendment 8, Revision No. 1, Appendix A.

Additionally, CEG provided specific information from LSCS's 72.212 Evaluation Report, Revision 9, indicating that during the design basis event of a non-mechanistic tip-over, LSCS's ISFSI would meet the requirements in 10 CFR 72.104, ''Criteria for radioactive materials in effluents and direct radiation from an ISFSI or MRS,'' and 10 CFR 72.106, ''Controlled area of an ISFSI or MRS.'' Specifically, CEG described that, in the highly unlikely event of a tip-over, any potential fuel damage from a non-mechanistic tip-over event would be localized, the confinement barrier would be maintained, and the shielding material would remain intact. Coupled with the distance of the LSCS ISFSI to the site area boundary, CEG concluded that compliance with 72.104 and 72.106 is not impacted by approving this exemption request.

The NRC staff reviewed the information provided by CEG and concludes that issuance of the exemption would not endanger life or property because the administrative controls that CEG has in place at the LSCS ISFSI sufficiently minimize the possibility of a tip-over or handling event, and that the containment boundary would be maintained in such an event. The staff confirmed that these administrative controls are documented in the technical specifications and UFSAR for the HI–STORM 100 Cask System CoC No. 1014, Amendment No. 8, Revision No. 1, that is used at the LSCS site. In addition, the staff confirmed that the information provided by CEG regarding LSCS's 72.212 Evaluation Report, Revision 9, demonstrates that the consequences of normal and accident conditions would be within the regulatory limits of the 10 CFR 72.104 and 10 CFR 72.106. The staff also determined that the requested exemption is not related to any aspect of the physical security or defense of the LSCS ISFSI; therefore, granting the exemption would not result in any potential impacts to common defense and security.

For these reasons, the NRC staff has determined that under the requested exemption, the storage system will continue to meet the safety requirements of 10 CFR part 72 and the offsite dose limits of 10 CFR part 20 and, therefore, will not endanger life or property or the common defense and security.

C. The Exemption Is Otherwise in the Public Interest

The proposed exemption would allow the four already loaded MPC–68M–CBS in the HI–STORM 100 Cask System to remain in storage at the LSCS ISFSI, and allow CEG to load four MPC–68M–CBS in the HI–STORM 100 Cask System in the future loading campaign beginning in June 2025, at the LSCS ISFSI, even though the CBS variant basket design is not part of the approved CoC No. 1014, Amendment No. 8, Revision No. 1. According to CEG, the exemption is in the public interest because being unable to load fuel into dry storage in the future loading campaign would impact CEG's ability to offload fuel from the LSCS reactor units, consequently impacting continued safe reactor operation.

CEG stated that further delaying the future loading campaign would impact its ability to effectively manage the margin to full core discharge capability in the LSCS Units 1 and 2 spent fuel pools. The low spent fuel pool capacity would make it difficult to refuel and present potential risks to fuel handling operations. In addition, a crowded spent fuel pool would challenge the decay heat removal demand of the pool and increase the likelihood of a loss of fuel pool cooling event and a fuel handling accident. Furthermore, CEG loading campaigns are scheduled based on availability of the specialized work force and equipment that is shared throughout the CEG fleet. These specialty resources support multiple competing priorities, including refueling outages, loading campaigns, fuel pool cleanouts, fuel inspections, fuel handling equipment upgrades and maintenance, fuel sipping, new fuel receipt, and crane maintenance and upgrades. Therefore, the available windows to complete cask loading campaigns are limited, and any delays would have a cascading impact on other scheduled specialized activities. CEG also considered requesting that Holtec provide eight (8) fully compliant canisters for the June 2025 campaign; however, CEG expects that Holtec will not be able to meet this request based on current manufacturing schedules. Additionally, CEG considered delaying the start of the 2025 campaign until Amendment 19 of the HISTORM 100 CoC is approved. This delay would result in the LSCS ISFSI campaign needing to pull specialty resources which would otherwise be required to support other CEG refueling and ISFSI campaigns.

For the reasons described by CEG in the exemption request, the NRC agrees that it is in the public interest to grant the exemption. If the exemption is not granted, in order to comply with the CoC, CEG would have to unload MPC–68M–CBS from the HI–STORM 100 Cask System at the LSCS ISFSI and reload into the older design MPC–68M to restore compliance with the terms, conditions, and specifications of the CoC. This would subject onsite personnel to additional radiation exposures and increase the risk of a possible fuel handling accident. Furthermore, the removed spent fuel would need to be placed in the spent fuel pool until it can be loaded into another storage cask or remain in the spent fuel pool if it is not permitted to be loaded into CBS casks for the future loadings. As described by CEG, this scenario would affect CEG's ability to effectively manage the margin to full core discharge capacity and present a potential reactivity management risk to fuel handling operations during pre- and post-refueling outages at LSCS. In addition, the rescheduling of the specialized resources for the future loading campaign would impact the operations of LSCS.

Therefore, the staff concludes that approving the exemption is in the public interest.

Environmental Consideration

The NRC staff also considered whether there would be any significant environmental impacts associated with the exemption. For this proposed action, the NRC staff performed an environmental assessment pursuant to 10 CFR 51.30. The environmental assessment concluded that the proposed action would not significantly impact the quality of the human environment. The NRC staff concluded that the proposed action would not result in any changes in the types or amounts of any radiological or non-radiological effluents that may be released offsite, and there would be no significant increase in occupational or public radiation exposure because of the proposed action. The environmental assessment and the finding of no significant impact was published on December 20, 2024 (89 FR 104234).

IV. Conclusion

Based on these considerations, the NRC has determined that, pursuant to 10 CFR 72.7, the exemption is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest. Therefore, the NRC grants CEG an exemption from the

requirements of §§ 72.212(a)(2), 72.212(b)(3), 72.212(b)(5)(i), 72.212(b)(11), and 72.214 with respect to the ongoing storage of four MPC–68M–CBS in the HI–STORM 100 Cask System and a future loading in the HI–STORM 100 Cask System of four new MPC–68M–CBS beginning in June 2025.

This exemption is effective upon issuance.

Dated: December 20, 2024.

For the Nuclear Regulatory Commission.

Yoira Diaz-Sanabria,

Chief, Storage and Transportation Licensing Branch, Division of Fuel Management, Office of Nuclear Material Safety, and Safeguards.

[FR Doc. 2025–00116 Filed 1–6–25; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–277 and 50–278; NRC–2024–0214; CEQ ID SEIS–429–00–000–1734688863]

Constellation Energy Generation, LLC; Peach Bottom Atomic Power Station, Units 2 and 3; Notice of Intent To Prepare a Supplement to the Supplemental Environmental Impact Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC, the Commission) staff will prepare a supplement to NUREG–1437, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants,'' Supplement 10, Second Renewal, ''Regarding Subsequent License Renewal for Peach Bottom Atomic Power Station Units 2 and 3,'' dated January 2020 (the final supplemental environmental impact statement (SEIS)) in order to complete its evaluation of the environmental impacts of the subsequent license renewal (SLR) of Renewed Facility Operating License Nos. DPR–44 and DPR–56 for Peach Bottom Atomic Power Station (Peach Bottom), Units 2 and 3, respectively. The supplement will address new information since the issuance of the final SEIS. A draft of the supplement will be issued for public comment.

DATES: January 7, 2025.

ADDRESSES: Please refer to Docket ID NRC–2024–0214 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–2024–0214. Go to *https://www.regulations.gov* and search for Docket ID NRC–2024–0214. 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.* The ADAMS accession number for each document referenced in this document (if it is available in ADAMS) is provided the first time that it is referenced.
- *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: Kevin Folk, telephone: 301–415–6944; email: *Kevin.Folk@nrc.gov* or Karen Loomis, telephone: 301–415–5142; email: *Karen.Loomis@nrc.gov.* Both are staff in the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Background

By letter dated July 10, 2018 (ADAMS Package Accession No. ML18193A689), Exelon Generation Company, LLC (now operating as Constellation Energy Generation, LLC (CEG)) submitted to the NRC an application, filed pursuant to section 103 of the Atomic Energy Act of 1954, as amended, and part 54 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Requirements for Renewal of Operating Licenses for Nuclear Power Plants,'' for subsequent renewed facility operating licenses with expiration dates of August 8, 2053, for Peach Bottom, Unit 2 and July 2, 2054, for Peach Bottom, Unit 3, which are 20 years beyond when the current renewed facility operating licenses expire. The SLR application included an environmental report (ADAMS Package Accession No. ML18271A185). Peach Bottom is located primarily in Peach Bottom Township, York County, Pennsylvania, near Delta, Pennsylvania.

A notice of receipt of the Peach Bottom SLR application was published in the **Federal Register** on August 1, 2018 (83 FR 37529). A notice of acceptance for docketing of the application and opportunity to request a hearing was published in the **Federal Register** on September 6, 2018 (83 FR 45285). A notice of intent to conduct a scoping process and prepare a SEIS was published in the **Federal Register** on September 10, 2018 (83 FR 45692). A notice of issuance of the draft SEIS and request for comment was published in the **Federal Register** on August 7, 2019 (84 FR 38676). A notice of issuance of the final SEIS was published in the **Federal Register** on January 31, 2020 (85 FR 5725). A notice of issuance of the subsequent renewed facility operating licenses was published in the **Federal Register** on March 11, 2020 (85 FR 14247). The issuance of the licenses was also supported by an NRC Record of Decision (ROD) (ADAMS Accession No. ML20024G429).

The final SEIS (ADAMS Accession No. ML20023A937) and the ROD document the NRC staff's environmental review, including its recommendation that the adverse environmental impacts of SLR for Peach Bottom are not so great that preserving the option of license renewal for energy-planning decisionmakers would be unreasonable. As discussed in the final SEIS and the ROD, the NRC staff considered the reasonably foreseeable environmental impacts of SLR for Peach Bottom, as well as a range of reasonable alternatives to SLR. As part of its environmental review, the NRC staff relied upon NUREG–1437, Revision 1, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants,'' dated June 2013 (ADAMS Package Accession No. ML13107A023) (the 2013 LR GEIS), to meet its obligations under the NRC's environmental protection regulations in 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,'' and the National Environmental Policy Act of 1969, as amended. Specifically, for issues classified as Category 1 (generic to all or a distinct subset of nuclear power plants) in the 2013 LR GEIS, the NRC staff did not identify new and significant information and, therefore, relied upon the conclusions of the 2013

LR GEIS for all those issues applicable to Peach Bottom. For issues classified as Category 2 (specific to individual nuclear power plants) in the 2013 LR GEIS, the NRC staff evaluated those issues applicable to Peach Bottom in the final SEIS.

On February 24, 2022, the Commission issued three memoranda and orders, Commission Legal Issuance (CLI)–22–02 (ADAMS Accession No. ML22055A496), CLI–22–03 (ADAMS Accession No. ML22055A527), and CLI–22–04 (ADAMS Accession No. ML22055A557), that addressed the NRC staff's environmental reviews in SLR proceedings for five nuclear power plants, including Peach Bottom. The Commission concluded that the 2013 LR GEIS, on which the NRC staff had relied, in part, for its environmental reviews of the SLR applications for the affected nuclear power plants, did not consider SLR. Therefore, the Commission determined that these environmental reviews were inadequate. Accordingly, the Commission directed the NRC staff to leave the Peach Bottom subsequent renewed facility operating licenses in place but to modify their expiration dates to reflect the end dates of the previous renewed facility operating licenses (*i.e.,* August 8, 2033, for Peach Bottom, Unit 2 and July 2, 2034, for Peach Bottom, Unit 3), which the staff did on March 25, 2022 (ADAMS Accession No. ML22073A207). The Commission affirmed this direction in CLI–22–07 (ADAMS Accession No. ML22154A217).

In CLI–22–03, the Commission directed the NRC staff to update the 2013 LR GEIS so that it covers nuclear power plant operation during the SLR period. The Commission stated that it believed the most efficient way to proceed would be for the NRC staff to update the 2013 LR GEIS and then take appropriate action with respect to pending SLR applications to ensure that the environmental impacts for the period of SLR are considered. Consistent with this Commission direction, on August 6, 2024, the NRC published the final rule ''Renewing Nuclear Power Plant Operating Licenses—Environmental Review'' (89 FR 64166). The final rule amended the NRC environmental protection regulations in 10 CFR part 51 to update the potential environmental impacts associated with the renewal of an operating license for a nuclear power plant for up to an additional 20 years, for either an initial license renewal or an SLR term. As part of this update, the NRC also issued Revision 2 to NUREG–1437 (the 2024 LR GEIS) (ADAMS Package Accession No. ML24087A133), which provides the technical basis for the final rule. Specifically, the 2024 LR GEIS supports the updated list of environmental issues and associated environmental impact findings contained in Table B–1 in Appendix B to Subpart A of the revised 10 CFR part 51 for both initial license renewal and SLR. The final rule became effective on September 5, 2024.

II. Discussion

Pursuant to the Commission's direction in CLI–22–04 to complete the National Environmental Policy Act of 1969, as amended, analysis for Peach Bottom SLR, the NRC staff will prepare a supplement to the final SEIS in accordance with 10 CFR 51.92. For the purposes of this supplement, the staff will assess whether new information since the final SEIS, including the 2024 final rule and the 2024 LR GEIS, warrants any modification to the NRC staff's previous recommendation that the adverse environmental impacts of SLR for Peach Bottom are not so great that preserving the option of license renewal for energy-planning decisionmakers would be unreasonable. In support of the development of the supplement, CEG submitted additional environmental information to the NRC by letter dated November 14, 2024 (ADAMS Package Accession No. ML24319A074). Together, the supplement and the previously issued final SEIS will evaluate all of the environmental impacts of continued operation during the SLR term for Peach Bottom, Unit 2 from August 8, 2033, to August 8, 2053, and for Peach Bottom, Unit 3 from July 2, 2034, to July 2, 2054. The draft supplement will be issued for public comment.

Dated: December 31, 2024.

For the Nuclear Regulatory Commission.

Stephen Koenick,

Chief, Environmental Project Management Branch 1, Division of Rulemaking, Environment, and Financial Support, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2024–31786 Filed 1–6–25; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2025–1008 and K2025–1007; MC2025–1009 and K2025–1008; MC2025–1011 and K2025–1010; MC2025–1025 and K2025–1024; MC2025–1026 and K2025–1025; MC2025–1027 and K2025–1026; MC2025–1028 and K2025–1027; MC2025–1029 and K2025–1028]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* January 7, 2025.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Public Proceeding(s)
III. Summary Proceeding(s)

I. Introduction

Pursuant to 39 CFR 3041.405, the Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to Competitive negotiated service agreement(s). The request(s) may propose the addition of a negotiated service agreement from the Competitive product list or the modification of an existing product currently appearing on the Competitive product list.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each such request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 and 39 CFR 3000.114 (Public Representative). Section II also

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service's request(s) identified in Section II, if any, are consistent with the policies of title 39. Applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3041. Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone advance Commission review. *See* 39 CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR 3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR 3041.405(c)–(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests.

II. Public Proceeding(s)

1. *Docket No(s).:* MC2025–1008 and K2025–1007; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 1210 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 27, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Almaroof Agoro; *Comments Due:* January 7, 2025.

2. *Docket No(s).:* MC2025–1009 and K2025–1008; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 1211 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 27, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Almaroof Agoro; *Comments Due:* January 7, 2025.

3. *Docket No(s).:* MC2025–1011 and K2025–1010; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 1213 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 27, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Samuel Robinson; *Comments Due:* January 7, 2025.

4. *Docket No(s).:* MC2025–1025 and K2025–1024; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 1219 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 27, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Samuel Robinson; *Comments Due:* January 7, 2025.

5. *Docket No(s).:* MC2025–1026 and K2025–1025; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 1220 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 27, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Kenneth Moeller; *Comments Due:* January 7, 2025.

6. *Docket No(s).:* MC2025–1027 and K2025–1026; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 1221 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 27, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Kenneth Moeller; *Comments Due:* January 7, 2025.

7. *Docket No(s).:* MC2025–1028 and K2025–1027; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 1222 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 27, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Elsie Lee-Robbins; *Comments Due:* January 7, 2025.

8. *Docket No(s).:* MC2025–1029 and K2025–1028; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 571 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 27, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Elsie Lee-Robbins; *Comments Due:* January 7, 2025.

III. Summary Proceeding(s)

None. *See* Section II for public proceedings.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2025–00002 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 576 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1017, K2025–1016.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00043 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby

gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1225 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1034, K2025–1033.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00051 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 577 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1019, K2025–1018.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00045 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 26, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1209 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1007, K2025–1006.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00035 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 26, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1208 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1006, K2025–1005.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00034 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1223 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1032, K2025–1031.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00049 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 26, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract*

1207 to Competitive Product List. Documents are available at *www.prc.gov,* Docket Nos. MC2025–1005, K2025–1004.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00033 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 579 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1036, K2025–1035.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00046 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 26, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1205 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1003, K2025–1002.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00031 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 26, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1203 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1001, K2025–1000.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00029 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 23, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1197 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–995, K2025–994.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00023 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 26, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1206 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1004, K2025–1003.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00032 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 573 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1014, K2025–1013.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00040 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 27, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1211 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1009, K2025–1008.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00037 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 26, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1204 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1002, K2025–1001.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00030 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 26, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1202 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1000, K2025–999.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00028 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 572 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1013, K2025–1012.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00065 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a

domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1216 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1022, K2025–1021.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00057 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 575 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1016, K2025–1015.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00042 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1224 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1033, K2025–1032.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00050 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 27, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1219 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1025, K2025–1024.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00060 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 581 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1031, K2025–1030.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00048 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1217 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1023, K2025–1022.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00058 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 27, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1210 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1008, K2025–1007.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00036 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 574 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1015, K2025–1014.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00041 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 23, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1199 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–997, K2025–996.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00025 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 580 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1030, K2025–1029.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00047 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 27, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1213 to Competitive Product List.* Documents are available at

www.prc.gov, Docket Nos. MC2025–1011, K2025–1010.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00054 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1215 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1021, K2025–1020.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00056 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 23, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1194 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–991, K2025–990.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00020 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 23, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1200 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–998, K2025–997.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00026 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 23, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 570 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–994, K2025–993.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00039 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 23, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1198 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–996, K2025–995.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00024 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 23, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1196 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–993, K2025–992.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00022 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 26, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1212 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1010, K2025–1009.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00053 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 23, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1195 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–992, K2025–991.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00021 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 20, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 569 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–990, K2025–989.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00038 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 27, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1220 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1026, K2025–1025.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00061 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1218 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1024, K2025–1023.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00059 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 577 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1018, K2025–1017.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00044 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1226 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1035, K2025–1034.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00052 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 26, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1201 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–999, K2025–998.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00027 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1214 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1020, K2025–1019.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00055 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 27, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 571 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1029, K2025–1028.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00064 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 27, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1221 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1027, K2025–1026.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00062 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* January 7, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 27, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1222 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2025–1028, K2025–1027.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025–00063 Filed 1–6–25; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–102074; File No. PCAOB–2024–05]

Public Company Accounting Oversight Board; Order Granting Approval on Constructive Requests To Withdraw From Registration

January 2, 2025.

I. Introduction

On November 14, 2024, the Public Company Accounting Oversight Board (the ''PCAOB'') filed with the Securities and Exchange Commission (the ''Commission''), pursuant to section 107(b)[1] of the Sarbanes-Oxley Act of 2002 (''SOX'') and section 19(b)[2] of the Securities Exchange Act of 1934 (the ''Exchange Act''), a proposed amendment to PCAOB Rule 2107, *Withdrawal from Registration* (the ''Amendment'').[3]

The Amendment was published for comment in the **Federal Register** on November 21, 2024.[4] The Commission received one comment letter from the public regarding the Amendment.[5] This order approves the Amendment, which we find to be consistent with the requirements of Title I of SOX and the rules and regulations issued thereunder and necessary or appropriate in the public interest or for the protection of investors.[6] The Amendment and the Commission's findings with respect thereto are discussed in further detail below.

II. Description of the Amendment

On November 14, 2024, the PCAOB adopted the Amendment.[7] The Amendment was preceded by a proposal on February 27, 2024, ''Proposals Regarding False and Misleading Statements Concerning PCAOB Registration and Oversight and Constructive Requests to Withdraw from Registration'' (the ''Proposing Release'').[8] The PCAOB's process to develop the Amendment included consideration of the comments received on the Proposing Release.

In the Notice of Filing of Proposed Rules,[9] the PCAOB stated that it was proposing the Amendment to enhance its registration program by creating a more accurate public record of registered public accounting firms in operation that wish to remain registered.[10] Under current rules, a registered public accounting firm can be removed from PCAOB registration only if the PCAOB either: (1) authorizes a withdrawal from registration based on a firm-initiated withdrawal request[11] or (2) imposes a disciplinary sanction revoking the firm's registration.[12] The

[1] 15 U.S.C. 7217(b).

[2] 15 U.S.C. 78s(b).

[3] *See Public Company Accounting Oversight Board; Notice of Filing of Proposed Rules on Constructive Requests to Withdraw from Registration,* Release No. 34–101644 (Nov. 15, 2024) [89 FR 92213 (Nov. 21, 2024)] (''Notice of Filing of Proposed Rules''), available at *https://www.sec.gov/files/rules/pcaob/2024/34-101644.pdf.*

[4] *Id.*

[5] A copy of the comment letter received on the Commission notice of the Amendment is available on the Commission's website at *https://www.sec.gov/comments/pcaob-2024-05/pcaob202405.htm.*

[6] *See* section 107(b)(4)(A) through (B) of SOX, 15 U.S.C. 7217(b)(4)(A) through (B).

[7] *See Constructive Requests to Withdraw from Registration,* PCAOB Release No. 2024–011 (Nov. 14, 2024) (''Adopting Release''), available at *https://assets.pcaobus.org/pcaob-dev/docs/default-source/rulemaking/docket-054/2024-011-registration.pdf?sfvrsn=35f8b138_2.*

[8] *See Proposals Regarding False or Misleading Statements Concerning PCAOB Registration and Oversight and Constructive Requests to Withdraw from Registration,* PCAOB Release No. 2024–001 (Feb. 27, 2024), *available at https://assets.pcaobus.org/pcaob-dev/docs/default-source/rulemaking/docket-054/2024-001-registration.pdf?sfvrsn=51869da_2.*

[9] Public Company Accounting Oversight Board; Notice of Filing of Proposed Rules on Constructive Requests to Withdraw from Registration, Release No. 34–101644 (Nov. 15, 2024) [89 FR 92213] (Nov. 21, 2024) (''Notice of Filing of Proposed Rules''), *available at https://www.sec.gov/files/rules/pcaob/2024/34-101644.pdf.*

[10] Notice of Filing of Proposed Rules at 7.

[11] Rule 2107 provides that a registered firm may request leave to withdraw from registration at any time by filing Form 1–WD.

[12] *See* Adopting Release at 2.

Amendment establishes a new procedural mechanism to address situations in which a registered firm has ceased to exist, is nonoperational, or no longer wishes to remain registered, as demonstrated by its failures, for at least two consecutive reporting years, to both (1) file annual reports (PCAOB Form 2, *Annual Report*) and (2) pay annual fees.

The PCAOB explains that, despite repeated reminders, a consistent group of firms neither files annual reports nor pays annual fees each year.[13] The presence of continuously delinquent firms on its list of registered firms hinders several regulatory objectives, including the PCAOB's ability to maintain an accurate public record of registered public accounting firms in operation and that wish to remain registered; to ensure that the information required on annual reports is being reported to the public and the PCAOB; to collect mandatory annual fees; and to efficiently use staff time and resources.[14] With the Amendment, the PCAOB aims to have a reasonable, efficient, and equitable way of identifying and removing from registration firms that have ceased to exist, are nonoperational, or no longer wish to remain registered.[15]

The Amendment, which adds paragraph (h) to existing Rule 2107, allows the PCAOB to treat failures to both (1) file annual reports (PCAOB Form 2, *Annual Report*) and (2) pay annual fees, for at least two consecutive reporting years, as a constructive request to withdraw from registration, and to initiate a process to deem the firm's registration withdrawn. To initiate the constructive withdrawal process, the PCAOB would furnish the firm with a written Notice of Delinquency and Impending Withdrawal (the ''Notice''), designed to provide the firm with notice of the process, the reason for commencement of the process, and its significance for the firm's registration.[16] The Notice would provide that the firm has 60 days to contact the PCAOB's registration staff by email to avoid withdrawal.[17] The Notice would be sent to the firm's primary contact, as identified in the firm's most recent filing with the PCAOB on Forms 1, 2, 3, or 4, via mail or commercial courier service, and the PCAOB would obtain a confirmation of actual or attempted delivery.[18] In addition to the mailed Notice, the PCAOB would also publish notice of the impending withdrawal on its public website.[19]

III. Effective Date

The Amendment will be effective initially for annual reports and annual fees that are due in 2025. This means that a registered firm that does not file an annual report and does not pay an annual fee in 2025 and 2026 could have its registration deemed withdrawn under Rule 2107(h) beginning in the fall of 2026.

IV. Discussion and Commission Findings

a. Existing Requirements and Current Non-Compliance

Section 102(d) of SOX requires each registered firm to submit an annual report to the PCAOB, while section 102(f) directs the PCAOB to assess and collect annual fees from each registered firm. Registration of firms and collecting annual fees to recover the cost of processing and reviewing registration applications and annual reports[20] are important components of the framework that enables the PCAOB to fulfill its investor protection mandate. Despite the express statutory requirements set forth in SOX, and repeated reminders from the PCAOB, however, a consistent group of firms neither files annual reports nor pays annual fees each year.[21] Moreover, PCAOB data indicate that, over time, a number of firms have persistently failed to fulfill both annual obligations, with more than 50 firms in noncompliance for at least six consecutive years and 13 firms in noncompliance for 14 consecutive reporting years.[22] The PCAOB states that this pattern of delinquency may be a result of firms that have ceased to exist, are non-operational, or otherwise do not wish to remain registered.[23]

The presence on PCAOB's registration list of firms that continuously fail to meet their basic obligations to maintain registration hinders several important PCAOB regulatory objectives: maintaining an accurate public record of registered public accounting firms in operation that wish to remain registered; ensuring that the public has access to information required by the annual report; collecting fees to support operation of its registration program; and efficiently using staff time and resources.[24] We note that the PCAOB currently has only two mechanisms for removing a registered public accounting firm from PCAOB registration: (1) authorizing a withdrawal from registration based on a firm-initiated withdrawal request[25] or (2) imposing a disciplinary sanction revoking the firm's registration.[26] Both mechanisms require some active engagement with the firms—they begin with either the firm initiating a request for withdrawal or the PCAOB's Office of Secretary providing notice of an Order Instituting Disciplinary Proceedings to the firm, which may not be possible in circumstances where the firm has ceased to exist, is non-operational, or for some other reason fails to comply with the basic requirements of registration.[27] By allowing the PCAOB to deem a firm's registration withdrawn under specified conditions and subject to certain procedural safeguards, the Amendment will help the PCAOB use its resources more efficiently and enhance its registration program by maintaining an accurate public record.

b. Rule 2107(h) Mechanism for Constructive Withdrawal and Procedural Protections

Under the new procedural mechanism in Rule 2107(h), the PCAOB would be able to deem a firm to have made a constructive request to withdraw if the firm has, for at least two consecutive reporting years, failed to both (1) file annual reports (PCAOB Form 2, Annual Report) and (2) pay annual fees.

Given that these represent two of the primary obligations of registered firms, we believe it is appropriate for the PCAOB to deem such failures as a constructive request to withdraw, and that in these circumstances the PCAOB should, with adequate procedural protections, take steps to withdraw such firm from registration. We note that the Rule 2107(h) process is discretionary, and the PCAOB has stated that its staff will continue to send warning letters each year to delinquent registered firms.[28]

The PCAOB concluded that the two-year benchmark is an appropriate proxy for firms that have ceased to exist, are non-operational, or no longer wish to remain registered, whereas one reporting year of delinquency was an

[13] *Id.* at 3.
[14] *Id.* at 4.
[15] *Id.* at 5.
[16] *Id.* at 14.
[17] *Id.* at 16.
[18] *Id.* at 15.
[19] *Id.*
[20] *See* SOX section 102(f), 15 U.S.C. 7212(f).
[21] *See* Adopting Release at 3.
[22] *Id.* at 10.
[23] *Id.* at 3.
[24] *Id.* at 4.
[25] *Id.* at 2.
[26] *Id.*
[27] *Id.* at 6. To initiate withdrawal from registration, a registered firm must file a Form 1–WD. *See* Rule 2107(d), while a revocation begins with the PCAOB's Office of the Secretary providing notice of an Order Instituting Proceedings to the firm. *See* PCAOB Rule 5201, *Notification of Commencement of Disciplinary Proceedings.*
[28] *See* Adopting Release at 14.

insufficient basis upon which to infer that a firm no longer wished to remain registered, and three or more years may unduly delay appropriate regulatory action.[29] We agree that two years of delinquencies in complying with the basic obligations for registration of paying fees and filing reports strikes the appropriate balance of regulatory efficiency and fairness to firms.

As described above in more detail, to initiate the constructive withdrawal process, the PCAOB would furnish the firm with a written Notice of Delinquency and Impending Withdrawal (the ''Notice''), to the firm's primary contact as identified in the firm's most recent PCAOB filing on Forms 1, 2, 3, or 4.[30] In addition to written notice, the PCAOB will also publish notice of the impending withdrawal on its public website.[31] We believe that these two methods are reasonably designed to provide firms with notice of the constructive withdrawal process, particularly in light of the fact that firms are required to maintain updated contact information.[32]

After the date the PCAOB sends the Notice, the firm has a 60-day period in which to send the PCAOB's registration staff an email indicating that it wishes to remain registered to stop the constructive withdrawal process. In evaluating the sufficiency of the procedural protections, we note that a firm will have approximately two months to evaluate and respond to the Notice and that it is not required to become current in its filings or fees to stop the constructive withdrawal process; the firm need only send an email to the staff to stop the constructive withdrawal process. This relatively low barrier to stopping the process should help ensure that firms that are in existence, operational, and wish to remain registered are not removed pursuant to this procedural mechanism, which is intended principally to address delinquencies that are due to firms ceasing to exist or operate, or otherwise no longer wishing to remain registered. In reaching this conclusion, however, we reiterate that, as observed by the PCAOB, violations of the PCAOB's reporting and fee requirements remain subject to enforcement.[33]

c. Withdrawal From Registration

If a firm does not notify the PCAOB that it wishes to remain registered in the 60-day period, the PCAOB is able to treat its consecutive failures for two years to file an annual report and pay annual fees as a constructive request to withdraw and to deem the firm's registration withdrawn. We note that, as a withdrawal-based mechanism, Rule 2107(h) is not a disciplinary proceeding or process, and, accordingly, withdrawal pursuant to this provision is not reported as a disciplinary sanction to any interested authorities.[34] Further, a firm whose registration is withdrawn, if it were in existence and operational notwithstanding the consecutive delinquencies triggering constructive withdrawal, would retain eligibility to perform work on audits of issuers or broker-dealers, provided such work remains below the substantial role threshold established by Rule 1001(p)(ii) and PCAOB Rule 2100.[35] Finally, a firm that has withdrawn from registration is permitted to reissue or give consent to the use of a prior audit report issued by the firm while registered with the PCAOB.[36]

The comment period closed on the Amendment on December 12, 2024. We received one comment letter, from an accounting firm. The commenter supported the Amendment, stating that the Amendment would create a more accurate public record of registered public accounting firms in operation that wish to remain registered.

V. Effect on Emerging Growth Companies

Section 103(a)(3)(C) of SOX requires that any rules of the PCAOB requiring mandatory audit firm rotation or a supplement to the auditor's report in which the auditor would be required to provide additional information about the audit and the financial statements of the issuer (auditor discussion and analysis) shall not apply to an audit of Emerging Growth Companies (''EGCs'').[37] The provisions of the Amendment do not fall into these categories.

Section 103(a)(3)(C) further provides that ''[a]ny additional rules'' adopted by the PCAOB after April 5, 2012, do not apply to audits of EGCs ''unless the Commission determines that the application of such additional requirements is necessary or appropriate in the public interest, after considering the protection of investors and whether the action will promote efficiency, competition, and capital formation.'' [38] In the Notice of Filing of Proposed Rules, the Board expressed its view that section 103(a)(3)(C) does not apply to the Amendment because the Amendment does not compose any additional requirements on audits. To the extent that section 103(a)(3)(C) does apply, however, the Board recommended that the Commission determine that the Amendment apply to audits of EGCs.[39]

With respect to the Commission's determination of whether the Amendment will apply to audits of EGCs, the PCAOB provided information, including data and analysis of EGCs, that sets forth its views as to why it believes the Amendment should apply to audits of EGCs. The PCAOB stated that an annual white paper prepared by its staff concluded that there were 3,031 companies that self-identified with the Commission as EGCs and filed audited financial statements in the preceding 18 months.[40] The PCAOB further stated that EGCs are likely to be newer companies, with audit committees having more limited experience in managing the process for finding and selecting a PCAOB-registered public accounting firm. Removal of consecutively delinquent firms, that are likely to be non-existent, non-operational, or no longer wish to be registered, could help reduce the search costs associated with making this decision. Further, the PCAOB indicated that it had no reason to believe that registered firms providing services to EGCs will incur costs that are greater than those incurred by firms providing services to non-EGCs, which are, in either case, likely to be incremental for operating firms that wish to remain registered. The PCAOB also noted that commenters agreed that the proposals generally should apply to audits of EGCs and that excluding the application of the proposals from audits of EGCs would be inconsistent with protecting the public interest.

[29] *Id.* at 13.

[30] *Id.* at 15.

[31] *Id.*

[32] *Id.*

[33] *Id.* at 13.

[34] *Id.* at 7.

[35] *Id.*

[36] *Id.*

[37] 15 U.S.C. 7213(a)(3)(C). The term ''emerging growth company'' is defined in section 3(a)(80) of the Exchange Act (15 U.S.C. 78c(a)(80)). *See also Inflation Adjustments under Titles I and III of the JOBS Act,* Release No. 33–11098 (Sept. 9, 2022) [87 FR 57394 (Sept. 20, 2022)], available at *https://www.sec.gov/files/rules/final/2022/33-11098.pdf.*

[38] *Id.*

[39] *See* Notice of Filing of Proposed Rules, Special Considerations for Audits of Emerging Growth Companies.

[40] *See* Notice of Filing of Proposed Rules (citing PCAOB Office of Economic and Risk Analysis, *Characteristics of Emerging Growth Companies and Their Audit Firms at November 15, 2022* (Feb. 20, 2024), *available at https://assets.pcaobus.org/pcaob-dev/docs/default-source/economicandriskanalysis/projectsother/documents/white-paper-on-characteristics-of-emerging-growth-companies-as-of-nov-15-2022.pdf?sfvrsn=a8294f3_4*).

We agree with the PCAOB's assessment as to the costs and benefits of the Amendment to EGCs. In particular, we agree that the Amendment may be of particular benefit to EGCs where audit committees may have less experience searching for and engaging audit firms, and may stand to benefit most from improved data quality as it relates to auditors. Accordingly, to the extent that section 103(a)(3)(C) applies, and after considering the protection of investors and whether the action will promote efficiency, competition, and capital formation, we believe there is a sufficient basis to determine that applying the Amendment to the audits of EGCs is necessary or appropriate in the public interest.

VI. Conclusion

The Commission has reviewed and considered the Amendment, the information submitted therewith by the PCAOB, the comment letter received, and the recommendation of the Commission's staff. The Commission concludes that the determinations made by the PCAOB as described in the Adopting Release are reasonable. The Amendment establishes an efficient procedural mechanism for the PCAOB to remove from registration firms that have ceased to exist, are non-operational, or no longer wish to remain registered. We agree that, as the PCAOB explains, the presence of continuously delinquent firms on the PCAOB's list of registered firms hinders several regulatory objectives, including its ability to maintain an accurate public record of registered public accounting firms in operation and that wish to remain registered; to ensure that the information required on annual reports is being reported to the public and the PCAOB; to collect mandatory annual fees; and to efficiently use PCAOB staff time and resources.[41] The Amendment will provide the PCAOB with an efficient mechanism to achieve these regulatory goals, while, through various procedural safeguards, balancing the need for reasonable and fair notice to firms that do indeed wish to maintain their registration.

Therefore, in connection with the PCAOB's filing and the Commission's review,

A. The Commission finds that the Amendment is consistent with the requirements of Title I of SOX and the rules and regulations thereunder and are necessary or appropriate in the public interest or for the protection of investors; and

B. Separately, to the extent that section 103(a)(3)(C) of SOX applies, the Commission finds that the application of the Amendment to the audits of EGCs is necessary or appropriate in the public interest, after considering the protection of investors and whether the action will promote efficiency, competition, and capital formation.

It is therefore ordered, pursuant to section 107 of SOX and section 19(b)(2) of the Exchange Act, that the Amendment (File No. PCAOB–2024–05) be and hereby is approved.

By the Commission.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2025–00119 Filed 1–6–25; 8:45 am]

BILLING CODE 8011–01–P

[41] *See* Adopting Release at 4.

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20701 and #20702; NORTH CAROLINA Disaster Number NC–20007]

Presidential Declaration Amendment of a Major Disaster for the State of North Carolina

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 5.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of North Carolina (FEMA–4827–DR), dated September 28, 2024.

Incident: Tropical Storm Helene.

DATES: Issued on December 31, 2024.

Incident Period: September 25, 2024 through December 18, 2024.

Physical Loan Application Deadline Date: February 6, 2025.

Economic Injury (EIDL) Loan Application Deadline Date: June 30, 2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of North Carolina, dated September 28, 2024, is hereby amended to extend the deadline for filing applications for physical damages as a result of this disaster to February 6, 2025.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Alejandro Contreras,

Acting Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2025–00011 Filed 1–6–25; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF STATE

[Public Notice: 12629]

2026 United States' Host Year of the G20

SUMMARY: The Office of the Chief of Protocol at the Department of State invites U.S. cities to present proposals to host a series of meetings for the U.S. G20 2026 host year.

DATES: The deadline to submit proposals is 5 p.m. ET, Monday, February 3, 2025.

FOR FURTHER INFORMATION CONTACT: Questions about the proposal and submission process can be directed to *G20USHostYear2026@state.gov.* Point of contact is Tara A. Juliard, Senior Protocol Officer, Office of the Chief of Protocol, Major Events Division at 202–736–4996.

SUPPLEMENTARY INFORMATION: The Group of Twenty (G20) is a forum for international economic cooperation among the world's leading economies. The G20's purpose is to coordinate macroeconomic policy and financial responses, and to shape global governance on major economic issues.

The G20 was founded in 1999 after the Asian financial crisis as an informal forum for the Finance Ministers and Central Bank Governors of large and systemically important advanced and emerging economies to discuss international economic and financial stability issues. The G20 was upgraded to the level of Heads of State/Government in November 2008 in the wake of the global economic and financial crisis, when it became apparent that the necessary crisis coordination would only be possible at the highest political level. Since then, the G20 has become the premier forum for international economic cooperation. The G20 members represent around 85% of global output, over 75% of global trade, and about two-thirds of the world's population. Its members are 19 countries (Argentina, Australia, Brazil, Canada, China, France, Germany, India, Indonesia, Italy, Japan, Republic of Korea, Mexico, Russia, Saudi Arabia, South Africa, Türkiye, United Kingdom, and United States) and two regional bodies, the European Union (EU) and

African Union (AU). G20 members meet regularly to discuss a range of issues, including macroeconomic policy, trade, sustainable development, health, agriculture, energy, environment, climate change, and anti-corruption. The G20 does not have a permanent secretariat or staff. Instead, the G20 Presidency rotates annually among the member countries.

The United States will assume the Presidency from December 1, 2025, through November 30, 2026. During its Presidency, the United States will be responsible for hosting a series of high-level meetings throughout the year to include multiple working groups and ministerials, culminating in a Leaders' Summit in November 2026.

Schedule: The host year will have clusters of meetings throughout the year. Please find below the proposed schedule.

* Please Note, this notional schedule is subject to change:

February 2026	Mid/Late February; 2.5 weeks of meetings.
March 2026	Mid/Late March; 2.5 weeks of meetings.
May 2026	Anytime; 2 weeks of meetings.
June 2026	Early to Mid/Late June; 2.5 weeks of meetings.
July 2026	Mid/Late July; 2.5 weeks of meetings.
September 2026	Early to Mid/Late September; 3 weeks of meetings.
October 2026	Early/Mid October; 3 weeks of meetings.

Proposal Preparation: Proposals must be submitted by email not later than the deadline listed in the **DATES:** section, with the naming convention of ''CITY, STATE, PROPOSAL for X MONTH OF MEETINGS of the 2026 G20 Host Year'' from a verified State/territory or municipal government email address to *G20USHostYear2026@state.gov*. The proposal must be A SINGLE PDF, and supporting documentation (attachments, videos, video presentations, presentations) should be identified as complete URLs in the PDF.

All information in the proposal, including price quotes, must be valid for 60 days after the due date of January 31, 2025. Notification must be given to the Office of the Chief of Protocol points of contact if pricing in the proposal changes during the review process.

The proposal should include all of the sections listed below and be clearly marked.

Proposal Sections:

I. Executive Summary

This summary should include the following topics:

a. An executive summary that includes a description of the city and/or region, local attractions, and level of community support for hosting events and why your city would be the ideal location for the G20 meetings. Please include as much detail as possible on ways in which your city is uniquely qualified to host the G20 meetings from a policy, economic, or trade perspective.

b. A past performance statement that indicates the city's successful experience hosting large meetings and events. Please also provide examples of large international or foreign diplomatic events hosted in the past.

c. List of local city officials who would be instrumental in partnering with the Department of State in the planning of the G20 meetings, including but not limited to the mayor's and governor's offices, airport officials, security officials. and staff from the recommended venues and tourism bureau who would be the planners' principal points of contact. Endorsements in writing from local officials are welcome and encouraged (see below for types to include).

d. Description of experiences creating host committees that serve to partner with the vendors and companies you have worked with in the past on events, conferences, and meetings. For the G20, each of the selected cities should anticipate they will be asked to organize a host committee to liaise with the Federal Government to support the meetings and develop opportunities to amplify the city and showcase it in various ways.

II. Letter of Support

Please include two or more of the following letters:

a. Letter of support from the mayor or city's senior elected official(s).

b. Letter of support from the State governor.

c. Letter(s) of support from local civic and business groups such as Chambers of Commerce.

III. Primary Event (Meeting) Venue(s)

Propose the venue(s) that is available during the time period and the city strongly recommends as the ideal site to host the two to three weeks of international multilateral meetings.

Requirements: The U.S. Government requires a minimum of five (5) full days to build the site on the front end before the first official meeting takes place and must assume acquisition of the entire proposed property for security reasons. All other clients must be vacated by the time the U.S. Government gains access to the venue spaces through the duration of the production strike unless previously negotiated between the Department of State Office of the Chief of Protocol and the city. The U.S. Government requires a minimum of two (2) full days to strike the meetings after the last official meeting has concluded. Cities are welcome to bid to host more than one set of the meetings if the timing works and could be selected to host up to two (2) of the meeting clusters if a city bids to host more than one meeting cluster. It is unlikely that one city would be selected to host more than two meeting clusters.

The main meeting venue needs to fulfill the following requirements:

Room type	Quantity	Capacity	Duration
		February 2026	
Meeting Room	3	Hollow Square for 60–80. Backbencher seating for 100 total: to be set in 1 row with classroom tables behind the main table on 3 sides and 2 rows of tables behind the 4th side.	3 weeks (includes build & strike).
Multi-Purpose Room	3	Hollow Square for 20 or Boardroom for 20	3 weeks (includes build & strike).
Listening Room	2	Classroom setup for 450	3 weeks (includes build & strike).

Room type	Quantity	Capacity	Duration
Overflow Listening room	1	Classroom setup for 1,000 (like an auditorium) (either one space or 2 spaces that accommodate that number).	1 Week (includes build & strike).
Bilateral Meeting Rooms	20	Boardroom for 20	3 weeks (includes build & strike).
Production Spaces	2–3	Workspace to accommodate 50 at tables	3 weeks (includes build & strike).
Workspaces	2	Classroom setup for 50	3 weeks (includes build & strike).
Lounge Space	1–2	Open space with lounge furniture and high boys to accommodate 500 (either one space or 2 spaces that can accommodate that number).	3 weeks (includes build & strike).
Catering/Meal Spaces	1–2	Banquet style seating of 600, (either one space or 2 spaces that can accommodate that number).	3 weeks (includes build & strike).
Overflow Lunch Space	1	Banquet style seating of 1,000	1 Week (includes build & strike).
VIP Catering Lunch Space	1	Banquet style or King Table for up to 100	1 Week (includes build & strike).
External Partner Meeting Room	1–2	Hollow Square for 40. Backbencher seating for 80	1 Week (includes build & strike).
Press Conference Rooms	3	Theater style with stage to accommodate 150	3 weeks (includes build & strike).
Media Space	1	Workspace to accommodate 150 at tables	3 weeks (includes build & strike).
March 2026			
Meeting Room	3	Hollow Square for 40–60. Backbencher seating for 150: to be set in 3 rows with classroom tables.	3–4 weeks (includes build & strike).
Multi-Purpose Room	3	Hollow Square for 20 or Boardroom for 20	3–4 weeks (includes build & strike).
Listening Room	1	Classroom setup to accommodate 100	1 Week (includes build & strike).
Bilateral Meeting Rooms	20	Boardroom for 20	3–4 weeks (includes build & strike).
Seminar Rooms	1–2	Theater style with stage to accommodate 450	1 Week (includes build & strike).
Production Spaces	2–3	Workspace to accommodate 50 at tables	3–4 weeks (includes build & strike).
Workspaces	2	Classroom setup for 50	3–4 weeks (includes build & strike).
Lounge Space	1–2	Open space with lounge furniture and high boys to accommodate 500 (either one space or 2 spaces that can accommodate that number).	3–4 weeks (includes build & strike).
Catering/Meal Spaces	1–2	Banquet style seating of 600, (either one space or 2 spaces that can accommodate that number).	3–4 weeks (includes build & strike).
May 2026			
Meeting Room	3	Hollow Square for 40–60. Backbencher seating for 150: to be set in 3 rows with classroom tables.	3 weeks (includes build & strike).
Multi-Purpose Room	3	Hollow Square for 20 or Boardroom for 20	3 weeks (includes build & strike).
Overflow Listening room	1	Theater to accommodate 1,000	1 Week (includes build & strike).
Bilateral Meeting Rooms	20	Boardroom for 20	3 weeks (includes build & strike).
Production Spaces	2–3	Workspace to accommodate 50 at tables	3 weeks (includes build & strike).
Workspaces	2	Classroom setup for 50	3 weeks (includes build & strike).
Lounge Space	1–2	Open space with lounge furniture and high boys to accommodate 500 (either one space or 2 spaces that can accommodate that number).	3 weeks (includes build & strike).
Catering/Meal Spaces	1–2	Banquet style seating of 600, (either one space or 2 spaces that can accommodate that number).	3 weeks (includes build & strike).
June 2026			
Meeting Room	3	Hollow Square for 40–60. Backbencher seating for 150: to be set in 3 rows with classroom tables.	3–4 weeks (includes build & strike).
Multi-Purpose Room	3	Hollow Square for 20 or Boardroom for 20	3–4 weeks (includes build & strike).
Listening Room	1	Classroom setup to accommodate 100	1 Week (includes build & strike).

Room type	Quantity	Capacity	Duration
Bilateral Meeting Rooms	20	Boardroom for 20	3–4 weeks (includes build & strike).
Seminar Rooms	1–2	Theater style with stage to accommodate 450	1 Week (includes build & strike).
Production Spaces	2–3	Workspace to accommodate 50 at tables	3–4 weeks (includes build & strike).
Workspaces	2	Classroom setup for 50	3–4 weeks (includes build & strike).
Lounge Space	1–2	Open space with lounge furniture and high boys to accommodate 500 (either one space or 2 spaces that can accommodate that number).	3–4 weeks (includes build & strike).
Catering/Meal Spaces	1–2	Banquet style seating of 600, (either one space or 2 spaces that can accommodate that number).	3–4 weeks (includes build & strike).
July 2026			
Meeting Room	3	Hollow Square for 60–80. Backbencher seating for 100 total: to be set in 1 row with classroom tables behind the main table on 3 sides and 2 rows of tables behind the 4th side.	3 weeks (includes build & strike).
Multi-Purpose Room	3	Hollow Square for 20 or Boardroom for 20	3 weeks (includes build & strike).
Listening Room	2	Classroom setup for 450	3 weeks (includes build & strike).
Bilateral Meeting Rooms	20	Boardroom for 20	3 weeks (includes build & strike).
Production Spaces	2–3	Workspace to accommodate 50 at tables	3 weeks (includes build & strike).
Workspaces	2	Classroom setup for 50	3 weeks (includes build & strike).
Lounge Space	1–2	Open space with lounge furniture and high boys to accommodate 500 (either one space or 2 spaces that can accommodate that number).	3 weeks (includes build & strike).
Catering/Meal Spaces	1–2	Banquet style seating of 600, (either one space or 2 spaces that can accommodate that number).	3 weeks (includes build & strike).
Overflow Lunch Space	1	Banquet style seating of 1,000	1 Week (includes build & strike).
VIP Catering Lunch Space	1	Banquet style or King Table for up to 100	1 Week (includes build & strike).
External Partner Meeting Room	1–2	Hollow Square for 40 Backbencher seating for 80	1 Week (includes build & strike).
Press Conference Rooms	3	Theater style with stage to accommodate 150	4–5 weeks (includes build & strike).
Media Space	1	Workspace to accommodate 150 at tables	4–5 weeks (includes build & strike).
September 2026			
Meeting Room	4	Hollow Square for 40–60. Backbencher seating for 150: to be set in 3 rows with classroom tables.	4–5 weeks (includes build & strike).
Multi-Purpose Room	4	Hollow Square for 20 or Boardroom for 20	4–5 weeks (includes build & strike).
Listening Room	1	Classroom setup to accommodate 100	4–5 weeks (includes build & strike).
Bilateral Meeting Rooms	20	Boardroom for 20	4–5 weeks (includes build & strike).
Seminar Rooms	1–2	Theater style with stage to accommodate 450	4–5 weeks (includes build & strike).
Production Spaces	2–3	Workspace to accommodate 50 at tables	4–5 weeks (includes build & strike).
Workspaces	2	Classroom setup for 50	4–5 weeks (includes build & strike).
Lounge Space	1–2	Open space with lounge furniture and high boys to accommodate 600 (either one space or 2 spaces that can accommodate that number).	4–5 weeks (includes build & strike).
Catering/Meal Spaces	1–2	Banquet style seating of 800, (either one space or 2 spaces that can accommodate that number).	4–5 weeks (includes build & strike).
VIP Catering Lunch Space	1	Banquet style or King Table for 80	4–5 weeks (includes build & strike).
Press Conference Rooms	3	Theater style with stage to accommodate 150	4–5 weeks (includes build & strike).
Media Space	1	Workspace to accommodate 150 at tables	4–5 weeks (includes build & strike).

Room type	Quantity	Capacity	Duration
October 2026			
Meeting Room	3–4	Hollow Square for 40–60. Backbencher seating for 150: to be set in 3 rows with classroom tables.	4–5 weeks (includes build & strike).
Multi-Purpose Room	3	Hollow Square for 20 or Boardroom for 20	4–5 weeks (includes build & strike).
Listening Room	2	Classroom setup to accommodate 250 each	4–5 weeks (includes build & strike).
Bilateral Meeting Rooms	25	Boardroom for 20	4–5 weeks (includes build & strike).
Production Spaces	2–3	Workspace to accommodate 50 at tables	4–5 weeks (includes build & strike).
Workspaces	2	Classroom setup for 50	4–5 weeks (includes build & strike).
Lounge Space	1–2	Open space with lounge furniture and high boys to accommodate 600 (either one space or 2 spaces that can accommodate that number).	4–5 weeks (includes build & strike).
Catering/Meal Spaces	1–2	Banquet style seating of 800 (either one space or 2 spaces that can accommodate that number).	4–5 weeks (includes build & strike).
VIP Catering Lunch Space	1	Banquet style or King Table for 80	4–5 weeks (includes build & strike).
Press Conference Rooms	3	Theater style with stage to accommodate 150	4–5 weeks (includes build & strike).
Media Space	1	Workspace to accommodate 150 at tables	4–5 weeks (includes build & strike).

IV. Event Spaces

More than one reception or dinner will be hosted in the selected city during the meetings. Therefore, please provide a full description of large venue(s) that can be used for large meetings/events and are available within the proposed timetable in which the city is interested in bidding to host. Please provide several options to include photos of the venues that show them in use for receptions and dinners. Be sure to conduct market research that none of these venues have any questionable associations or legal issues. The venues should be able to host the following types of events:

a. Locations for large Welcome Reception(s) of approximately 300 guests.

b. Locations for Ministerial Level Dinner(s) for approximately 100 high level guests.

c. Locations for Ministerial Level Reception(s) for approximately 200 guests.

d. Locations for Cultural and Topic-Specific Experience(s)

○ Universities and research facilities;

○ U.S. companies with factories and production facilities that have trade and investment ties to G20 countries;

○ Tourist Attractions for group outings (museums, historical sites, boat rides to iconic destinations, sporting events, etc.)—purpose would be so that foreign delegations experience the city first-hand to enrich the meeting experience.

V. Accommodations

When proposing a meeting venue, please include a detailed description of four- and five-star hotels in proximity to the venue with room number capacity (including suites) and room rates.

During the meeting cluster dates, the number of hotel rooms needed for meeting guests will fluctuate from 500–1,500 rooms (this is not cumulative).

a. Identify number of sleeping room nights that could be accommodated by U.S. Government per diem room rate.

b. The U.S. Government (Department of State) will select one hotel closest to the venue to serve as the U.S. Government Trip Hotel.

i. This hotel will have a contract agreement between the hotel property and the U.S. Government (Department of State) for meeting/function spaces and room nights.

ii. Some designed room nights will be self-pay by the occupant; others will be designated and paid via master account.

c. Room builds for these meetings will fluctuate throughout the weeks of the meetings with various groups arriving and departing for meeting at different days/times.

d. A booking system for the Foreign Delegations, via Letter of Intent, will be based upon bell-curve booking capability allowing reservation of only the rooms needed thus avoiding costly cancellation or changes later.

e. Other participating U.S. Government agencies (Department of Treasury, Commerce, or other) may deploy implementers who will establish room bocks in identified hotel properties.

i. Payment would be via occupant self-pay or via implementer contract as determined necessary and contracted by the participating agency or Foreign Delegations.

IV. Airport

When proposing please include the frequency and destinations of flights of the nearest airports.

a. An international airport with frequent and consistent daily connections to and from countries from the continents of Africa, Asia, Europe, and South America.

b. An international airport with detailed description of exclusive meet and great areas involving transportation holding/waiting, loading, and rally points around the commercial air operations.

V. Transportation

a. List of at least three (3) reputable charter shuttle/bus companies the U.S. Government can contract with to provide transportation to the delegates.

b. List of three (3) transportation companies that can provide car service.

c. List of parking lots that can accommodate transportation modes that shuttle G20 guests and host delegations.

d. List public transportation available in the city, and how it can be used for foreign delegates to facilitate arrival and departures at the main meeting/event site.

VI. Security

Brief statement of the current security of the city and what sort of city resources would be available to ensure

foreign delegations would be safe while there.

Presentations and Site Visits: After an initial review of all proposals in February 2025, to include a virtual presentation in early-to-mid February, cities will be identified to move to the next round of review. Prior to final selection, the Office of the Chief of Protocol at the Department of State may also request a site visit of the city to review the venues and meet with city officials who are part of the proposal.

(Authority: 22 U.S.C. 2651a, 2656; 5 U.S.C. 552(a))

Tara A. Juliard,

Senior Protocol Officer, Office of the Chief of Protocol, Major Events Division, Department of State.

[FR Doc. 2025–00018 Filed 1–6–25; 8:45 am]

BILLING CODE 4710–20–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36807]

Carload Express, Inc.—Control Exemption—The Maryland and Delaware Railroad Company

By petition filed on October 30, 2024, Carload Express, Inc. (Carload), a noncarrier, seeks an exemption under 49 U.S.C. 10502 from the prior approval requirements of 49 U.S.C. 11323 to acquire control of The Maryland and Delaware Railroad Company (MDDE), a Class III rail carrier, through the purchase of the outstanding equity shares in MDDE from Old Line Holdings, Inc. (Old Line). As discussed below, the Board will grant Carload's petition for exemption.

Background

MDDE, a wholly owned subsidiary of Old Line, is a Class III rail carrier that operates three unconnected rail lines between Delaware and Maryland: (1) the Centreville/Chesterton Line extending from milepost 1.0 at Townsend, Del., to milepost 34.0 at Centreville, Md., and from milepost 0.0 (milepost 9.3 on the Centreville segment) at Massey, Md., to milepost 18.82 at Worton, Md.; (2) the Seaford Line extending from milepost 2.3 at Seaford, Del., to milepost 24.24 at Linkwood, Md.; and (3) the Snow Hill Line extending from milepost 39.0 at Frankford, Del., to milepost 65.7 at Snow Hill, Md., which MDDE also owns. (*Id.* at 3); *see Md. & Del. R.R.—Acquis. Exemption—Snow Hill Shippers Ass'n, Inc.,* FD 33772 (STB served Feb. 24, 2000).

Carload is a noncarrier holding company that currently controls three Class III rail carriers: two operating in southwestern Pennsylvania,[1] and the Delmarva Central Railroad Company (DCR), which leases or operates approximately 187 miles of rail line on the Delmarva Peninsula in Delaware, Maryland, and Virginia. (Pet. 1–2.) According to Carload, DCR operates a rail line that connects with each of the rail lines operated by MDDE,[2] and therefore the proposed control transaction does not qualify for the class exemption under 49 CFR 1180.2(d)(2). (Pet. 1, 3.)

Concurrent with Carload's petition, Old Line filed a verified notice of exemption to acquire from MDDE and operate an approximately 23.7-mile portion of the Snow Hill Line (Snow Hill South Line). Verified Notice, *Old Line Holding Co.—Acquis. & Operation Exemption—Line of the Md. & Del. R.R.,* FD 36806. Notice of the exemption was served and published in the **Federal Register** on November 15, 2024 (89 FR 90343). According to the petition, Old Line's acquisition of the Snow Hill South Line from MDDE would occur immediately prior to Carload's acquisition of MDDE from Old Line, pursuant to a purchase agreement dated August 1, 2024. (Pet. 1, 4.) The purchase agreement also contemplates that DCR would acquire from MDDE the remaining three-mile portion of the Snow Hill Line (Snow Hill North Line).[3] (Pet. 4.) In the petition, Carload explains that the structure of the transactions ''accommodates certain tax treatment of the Snow Hill North Line acquisition'' and would divide ownership of the Snow Hill Line between DCR and Old Line. (*Id.*) Carload states that, after it acquires control of MDDE, MDDE would continue operating the Centreville/Chesterton and Seaford Lines.[4] (Pet. 4.)

According to Carload, upon consummation of the proposed transaction, the rail operations of MDDE and DCR would be closely coordinated and MDDE's operations would be supported by Carload and DCR. (*Id.* at 5.) Carload states that it does not anticipate service level changes on the Centreville/Chesterton and Seaford Lines. (*Id.*) Carload also states that the proposed transaction would not result in any shipper losing rail service or existing competitive options. (*Id.*) According to Carload, DCR serves as MDDE's sole physical link to the remainder of the national rail system and all traffic currently moving over MDDE also moves over DCR's rail line, which would continue after Carload acquires control of MDDE. (*Id.* at 3, 5.) Carload also states that the proposed transaction would not alter the arrangement that, as handling carriers for Norfolk Southern Railway Company (NSR), MDDE and DCR do not control pricing on interline traffic with NSR. (*Id.* at 4–5.)

Carload states that the proposed transaction would ''bring to MDDE the strengths and resources of an established short-line operator'' while preserving MDDE's current service. (*Id.* at 7.) Carload further states that the proposed transaction would permit coordination between the rail carriers, thereby ''enhancing effective rail management and the economic benefits of MDDE's service.'' (*Id.*) According to Carload, the proposed transaction would not adversely impact competition, as MDDE and DCR do not serve common industries where they connect. (*Id.* at 8.) Carload also states that the proposed transaction would not impact competitive options because all MDDE traffic would continue moving over DCR's rail line. (*Id.* at 5, 8.) According to Carload, ''MDDE will simply be incorporated into the Carload family of short-line carriers,'' and shippers may benefit from greater efficiencies as a result. (*Id.* at 8.)

Carload seeks expedited consideration so that the proposed transaction—along with all related transactions involving Carload, DCR, MDDE, and Old Line—can be consummated no later than January 31, 2025. (*Id.* at 10.) According to Carload, an expedited decision would allow the parties to avoid multiple closings. (*Id.*)

Discussion and Conclusions

Under 49 U.S.C. 11323(a)(5), prior approval by the Board is required for the

[1] Carload controls Allegheny Valley Railroad Company and Southwest Pennsylvania Railroad Company. *See Carload Express, Inc.—Continuance in Control Exemption—Delmarva Cent. R.R.,* FD 36072 (STB served Dec. 2, 2016); *see also Katahdin Railcar Servs. LLC—Change in Operators Exemption—Ohio Terminal Ry.,* FD 36487 (STB served Mar. 30, 2021).

[2] According to Carload, MDDE and DCR connect at Townsend, Seaford, and Frankford, Delaware. (Pet. 3.)

[3] DCR filed a verified notice of exemption for the proposed acquisition, and notice of the exemption was served and published in the **Federal Register** on October 4, 2024 (89 FR 80982). *See Delmarva Cent. R.R.—Acquis. Exemption—Line of the Md. & Del. R.R.,* FD 36805, slip op. at 1 (STB served Oct. 4, 2024) (noting DCR stated that it would operate the Snow Hill North Line). According to the petition, following DCR's proposed acquisition of the Snow Hill North Line and Old Line's proposed acquisition of the Snow Hill South Line, ''the current DCR–MDDE interchange at Frankford will be replaced by a DCR-Old Line interchange at Selbyville.'' (Pet. 4 n.10.)

[4] Carload states that these lines are owned by the Maryland Transit Administration and are operated by MDDE pursuant to a modified certificate of public convenience and necessity. (Pet. 3); *see Md. & Del. R.R.—Modified Rail Certificate,* FD 29830 (ICC served Feb. 9, 1982).

acquisition of control of a rail carrier by a person that is not a rail carrier but that controls any number of rail carriers. Under 49 U.S.C. 10502(a), however, the Board shall, to the maximum extent consistent with U.S. Code Title 49, subtitle IV, part A, exempt a transaction from regulation if it finds that (1) regulation is not necessary to carry out the rail transportation policy (RTP) of 49 U.S.C. 10101, and (2) either (a) the transaction or service is limited in scope, or (b) regulation is not needed to protect shippers from the abuse of market power.

In this case, an exemption from the prior approval requirements of 49 U.S.C. 11323–25 is consistent with the standards of 49 U.S.C. 10502. Detailed scrutiny of the proposed transaction through an application for review and approval under sections 11323–25 is not necessary to carry out the RTP. An exemption would promote the RTP by minimizing the need for federal regulatory control over the proposed transaction, 49 U.S.C. 10101(2); ensuring the continuation of a sound rail transportation system that would continue to meet the needs of the public, 49 U.S.C. 10101(4); fostering sound economic conditions in transportation, 49 U.S.C. 10101(5); reducing regulatory barriers to entry into and exit from the industry, 49 U.S.C. 10101(7); encouraging efficient management of railroads, 49 U.S.C. 10101(9); and providing for the expeditious resolution of this proceeding, 49 U.S.C. 10101(15). Other aspects of the RTP would not be adversely affected.

Regulation of the transaction is not needed to protect shippers from an abuse of market power.[5] MDDE and DCR do not serve common industries where they connect at Townsend, Seaford, and Frankford. (Pet. 8.) Further, the common control of MDDE and DCR would not reduce competitive options for shippers, as all MDDE traffic currently moves over DCR's line and would continue to do so following Carload's acquisition of MDDE. (*Id.* at 5, 8.) Indeed, because DCR is MDDE's ''sole physical link'' to the remainder of the interstate rail network, there is no risk that Carload may foreclose interchange between MDDE and other connecting carriers. (*Id.* at 3, 8 n.12; *see also id.,* Ex. A (showing MDDE interchanges).) Shippers may also benefit from improved coordination between MDDE and DCR. Moreover, no shipper (or any other entity) has objected to the proposed control transaction. Nevertheless, to ensure that the shippers are informed of our action, we will require Carload to serve a copy of this decision on all shippers on the Centreville/Chesterton, Seaford, and Snow Hill North Lines and certify to the Board that it has done so within five days of the service date of this decision.

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a carrier of its statutory obligation to protect the interests of 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. Therefore, because all the carriers involved in the proposed transaction are Class III carriers, the Board may not impose labor protective conditions.

The control transaction is exempt from environmental reporting requirements under 49 CFR 1105.6(c)(1)(i) because it will not result in any significant change in carrier operations. Similarly, the transaction is exempt from the historic reporting requirements under 49 CFR 1105.8(b)(3) because it will not substantially change the level of maintenance of railroad properties.

As indicated above, Carload seeks to be able to consummate this transaction and other related transactions together by no later than January 31, 2025. The Board finds that Carload's request is reasonable. Accordingly, the effective date of the exemption will be January 31, 2025. *See* 49 CFR 1121.4(e) (''Unless otherwise specified in the decision, an exemption generally will be effective 30 days from the service date of the decision.''). Petitions for stay must be filed by January 16, 2025. Petitions to reopen will be due by January 27, 2025.

It is ordered:

1. Under 49 U.S.C. 10502, the Board exempts from the prior approval requirements of 49 U.S.C. 11323–25 Carload's acquisition of control of MDDE through the purchase of the outstanding equity shares in MDDE from Old Line.

2. Notice of the exemption will be published in the **Federal Register**.

3. Carload shall serve a copy of the decision on all shippers on the Centreville/Chesterton, Seaford, and Snow Hill North Lines and certify to the Board that it has done so, by January 7, 2025.

4. The exemption will become effective on January 31, 2025. Petitions for stay must be filed by January 16, 2025. Petitions to reopen must be filed by January 27, 2025.

Decided: December 31, 2024.

By the Board, Board Members Fuchs, Hedlund, Primus, and Schultz.

Zantori Dickerson,

Clearance Clerk.

[FR Doc. 2025–00068 Filed 1–6–25; 8:45 am]

BILLING CODE 4915–01–P

[5] Given this finding, the Board need not determine whether the transaction is limited in scope. *See* 49 U.S.C. 10502(a).

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Internal Revenue Service (IRS) Information Collection Requests

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection requests 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. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before February 6, 2025 to be assured of consideration.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Melody Braswell by emailing *PRA@treasury.gov,* calling (202) 622–1035, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Internal Revenue Service (IRS)

1. Title: United States Gift (and Generation-Skipping Transfer) Tax Return.

OMB Number: 1545–0020.

Form Number: Form 709, 709–NA.

Abstract: Form 709 is used by individuals to report transfers subject to the gift and generation-skipping transfer taxes and to compute these taxes. The IRS uses the information to collect and enforce these taxes, to verify that the taxes are properly computed, and to compute the tax base for the estate tax. Form 709–NA is used to report certain transfers by a nonresident not a citizen

of the United States that are subject to the Federal gift tax and certain generation-skipping transfer (GST) taxes and to figure the tax due, if any, on those transfers. The Form 709–NA is also used to allocate the lifetime GST exemption to property transferred during a transferor's lifetime.

Current Actions: This collection is being revised to include Form 709–NA.

Type of Review: Revision to previously approved collection.

Affected Public: Individuals and household.

Estimated Number of Responses: 225,530.

Estimated Time per Respondent: 6 hours, 12 minutes.

Estimated Total Annual Burden Hours: 1,398,286.

2. Title: Declarations and Authorizations for Electronic Filing.

OMB Number: 1545–0967.

Form Number: 8453–EG, 8453–WH, 8879–EG, and 8879–WH.

Abstract: The IRS is actively engaged in encouraging e-filing and electronic documentation. The Form 8453 series is used to authenticate the electronically filed tax return, authorize the electronic return originator (ERO) or intermediate service provider (ISP) to transmit the return, and provide the taxpayer's consent to authorize electronic funds withdrawal for payment of taxes owed. The Form 8879 series is used authorize the taxpayer and ERO to sign the return using a personal identification number (PIN) and consent to an electronic funds withdrawal.

Current Actions: There is a change to the existing collection. Forms 8453–EG and 8879–EG are new forms developed for United States Gift (and Generation-Skipping Transfer) Tax Return.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals or households, and Business or other for-profit organizations.

Estimated Number of Responses: 226,400.

Estimated Time per Respondent: 1.99 hours.

Estimated Total Annual Burden Hours: 450,520.

Authority: 44 U.S.C. 3501 *et seq.*

Melody Braswell,

Treasury PRA Clearance Officer.

[FR Doc. 2024–31781 Filed 1–6–25; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0016]

Agency Information Collection Activity: Claim for Disability Insurance Benefits, Government Life Insurance

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Comments must be received on or before March 10, 2025.

ADDRESSES: Comments must be submitted through *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

Program-Specific information: Nancy Kessinger, 202–461–8900, *nancy.kessinger@va.gov.*

VA PRA information: Maribel Aponte, 202–461–8900, *vacopaperworkreduact@va.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Claim for Disability Insurance Benefits, Government Life Insurance—VA Form 29–357.

OMB Control No.: 2900–0016. https://www.reginfo.gov/public/do/PRASearch (Once at this link, you can enter the OMB Control Number to find the historical versions of this Information Collection).

Type of Review: Extension of a currently approved collection.

Abstract: This form is used by the policyholder to claim disability insurance benefits on S–DVI, NSLI and USGLI policies. The information requested is authorized by law, 38 U.S.C. 1912, 1915, 1922, 1942 and 1948.

Affected Public: Individuals and households.

Estimated Annual Burden: 14,175 hours.

Estimated Average Burden per Respondent: 1 hour and 45 minutes.

Frequency of Response: Once.

Estimated Number of Respondents: 8,100.

Authority: 44 U.S.C. 3501 *et seq.*

Dorothy Glasgow,

VA PRA Clearance Officer (Alt.), Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2025–00015 Filed 1–6–25; 8:45 am]

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Part II

Department of Energy

10 CFR Parts 429 and 430
Energy Conservation Program: Test Procedure for Central Air Conditioners and Heat Pumps; Final 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: Final rule.

SUMMARY: This final rule amends 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 is incorporating by reference the latest version of the relevant industry consensus test standard, AHRI 210/240–2024 (I–P) for 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''). DOE is incorporating by reference the new industry consensus test standard, AHRI 1600–2024 (I–P), for a new test procedure (''appendix M2'') for CAC/HPs that adopts 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 is amending certain provisions of DOE's regulations related to representations and enforcement for CAC/HPs.

DATES: The effective date of this rule is February 6, 2025. The amendments will be mandatory for product testing starting July 7, 2025. Manufacturers will be required to use the amended test procedure until the compliance date of any final rule establishing amended energy conservation standards based on the newly established test procedure. At such time, manufacturers will be required to begin using the newly established test procedure.

The incorporation by reference of certain publications listed in this rule is approved by the Director of the Federal Register on February 6, 2025.

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

A link to 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.

For further information on how to review the docket contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

FOR FURTHER INFORMATION CONTACT:

Dr. Pradeep Prathibha, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (240) 255–0630. 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) 586–4798. Email: *peter.cochran@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: DOE maintains previously approved incorporations by reference and incorporates by reference the following industry standards into 10 CFR parts 429 and 430:

AHRI Standard 210/240–2024 (I–P), Performance Rating of Unitary Air-conditioning and Air-source Heat Pump Equipment, copyright 2024 (''AHRI 210/240–2024'').

AHRI Standard 1600–2024 (I–P), Performance Rating of Unitary Air-conditioning and Air-source Heat Pump Equipment, copyright 2024 (''AHRI 1600–2024'').

Copies of AHRI 210/240–2024 and AHRI 1600–2024 can be obtained from the Air-Conditioning, Heating, and Refrigeration Institute (AHRI), 2311 Wilson Blvd., Suite 400, Arlington, VA 22201, (703) 524–8800, or online at: *www.ahrinet.org.*

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'').

ANSI/ASHRAE Standard 37–2009, Methods of Testing for Rating Electrically Driven Unitary Air-Conditioning and Heat Pump Equipment, ANSI-approved June 25, 2009 (''ASHRAE 37–2009'').

ANSI/ASHRAE Standard 116–2010, Methods of Testing for Rating Seasonal Efficiency of Unitary Air Conditioners and Heat Pumps, ANSI approved February 24, 2010 (''ANSI/ASHRAE 116–2010'').

Copies of ANSI/ASHRAE 16, ASHRAE 37–2009, and ANSI/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.N 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 the U.S. Department of Energy (''DOE'') is authorized to establish and amend energy conservation standards and test procedures. (42 U.S.C. 6292 (a)(3)) DOE's test procedure for CAC/HPs is currently prescribed at 10 CFR part 430, subpart B, appendix M1 (''appendix M1''). The following sections discuss DOE's authority to establish and amend the test procedure for CAC/HPs and relevant background information regarding DOE's consideration of the test procedure for this product.

A. Authority

The Energy Policy and Conservation Act, Pub. L. 94–163, as amended (''EPCA''),[1] authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317, as codified) Title III, Part B of EPCA [2] 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 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 under EPCA (42 U.S.C. 6295(s)), and (2) making other representations about the efficiency of those products (42 U.S.C. 6293(c)). Similarly, DOE must use these test procedures to determine whether the products comply with any 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 shall 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 (as determined by the Secretary) or period of use and shall not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3))

EPCA also requires that, at least once every seven 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.

DOE's regulations at 10 CFR 430.27 provide that any interested person may seek a waiver from the test procedure requirements if certain conditions are met. A waiver requires manufacturers to use an alternate test procedure in situations in which the DOE test procedure cannot be used to test the product or equipment, or use of the DOE test procedure would generate unrepresentative results. 10 CFR 430.27(a)(1). DOE's regulations at 10 CFR 430.27(l) require that as soon as practicable after the granting of any waiver, DOE will publish in the **Federal Register** a notice of proposed rulemaking (''NOPR'') to amend its regulations so as to eliminate any need for the continuation of such waiver. As soon thereafter as practicable, DOE will publish in the **Federal Register** a final rule. 10 CFR 430.27(l).

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 into the overall energy efficiency, energy consumption, or other

[1] 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 reflects the last statutory amendments that impact Parts A and A–1 of EPCA.

[2] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

energy descriptor, unless the current test procedure already incorporates the standby mode and off-mode energy consumption, or if such integration is technically infeasible. (42 U.S.C. 6295(gg)(2)(A)(i)–(ii)) If an integrated test procedure is technically infeasible, DOE must prescribe separate standby mode and off-mode energy use test procedures for the covered product, if a separate test is 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 [3] and IEC Standard 62087 [4] as applicable. (42 U.S.C. 6295(gg)(2)(A)) DOE is publishing this final rule in satisfaction of the seven-year review requirement specified in EPCA. (42 U.S.C. 6293(b)(1)(A))

B. Background

On April 5, 2024, DOE published in the **Federal Register** a notice of proposed rulemaking (''NOPR'') (''April 2024 NOPR'') proposing to update the Federal test procedure for CAC/HPs by: (1) incorporating by reference at appendix M1 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''). 89 FR 24206. Copies of the AHRI drafts were added to the docket for this rulemaking for review by interested parties.[5] [6] As stated in the April 2024 NOPR, if AHRI 210/240–202X Draft and AHRI 1600–202X Draft were to be finalized and formally adopted, DOE's intention would be to reference the final published version of AHRI 210/240 and AHRI 1600 in DOE's subsequent test procedure final rule. 89 FR 24206, 24209. DOE held a public meeting webinar on April 25, 2024 to discuss the proposed amendments to the CAC/HP test procedure presented in the April 2024 NOPR.

DOE received comments in response to the April 2024 NOPR from the interested parties listed in table I.1.

TABLE I–1—LIST OF COMMENTERS WITH WRITTEN SUBMISSIONS IN RESPONSE TO THE APRIL 2024 NOPR

Commenter(s)	Reference in this final rule	Comment No. in the docket	Commenter type
Air-Conditioning, Heating, and Refrigeration Institute	AHRI	25	Trade Association.
Pacific Gas and Electric Company, San Diego Gas and Electric, and Southern California Edison; collectively, the California Investor-Owned Utilities.	CA IOUs	32	Utilities.
Carrier Global Corporation	Carrier	29	Manufacturer.
Copeland LP	Copeland	31	Manufacturer.
Daikin Comfort Technologies North America Inc	Daikin	36 and 40	Manufacturer.
GE Appliances	GE Appliances	37	Manufacturer.
Heating, Air-conditioning & Refrigeration Distributors International	HARDI	26	Trade Association.
Johnson Controls	JCI	35	Manufacturer.
Appliance Standards Awareness Project, National Consumer Law Center, and New York State Energy Research and Development Authority.	Joint Advocates	30	Efficiency Organization, Consumer Advocacy Organization, and State Agency.
Keith Rice	Keith Rice	33	HVAC R&D Engineer.
Lennox International Inc	Lennox	24	Manufacturer.
LG Electronics U.S.A., Inc	LG	38	Manufacturer.
Mitsubishi Electric US	Mitsubishi	28	Manufacturer.
National Comfort Products	NCP	27	Manufacturer.
Northwest Energy Efficiency Alliance	NEEA	39	Efficiency Organization.
Rheem Manufacturing Company	Rheem	34	Manufacturer.

A parenthetical reference at the end of a comment quotation or paraphrase provides the location of the item in the public record.[7] To the extent that interested parties have provided written comments that are substantively consistent with any oral comments provided during the April 25, 2024 public meeting, DOE cites the written comments throughout this final rule. DOE did not identify any oral comments provided during the April 25, 2024, public meeting that are not substantively addressed by written comments.

In May 2024, AHRI finalized AHRI 210/240–202X Draft and AHRI 1600–202X Draft without substantial change, and published AHRI Standard 210/240–2024, ''Performance Rating of Unitary Air-conditioning and Air-source Heat Pump Equipment'' (''AHRI 210/240–2024''), and AHRI Standard 1600–2024, ''Performance Rating of Unitary Air-conditioning and Air-source Heat Pump Equipment'' (''AHRI 1600–2024''), respectively.

II. Synopsis of the Final Rule

In this final rule, DOE is updating its regulations for CAC/HPs by: (1) amending appendix M1 to incorporate by reference the latest industry standard, AHRI 210/240–2024, while maintaining the current efficiency metrics EER2, SEER2 and HSPF2; and (2) establishing a new appendix M2 that references the new industry test

[3] IEC 62301, *Household electrical appliances—Measurement of standby power* (Edition 2.0, 2011–01).

[4] IEC 62087, *Audio, video and related equipment—Methods of measurement for power consumption* (Edition 1.0, Parts 1–6: 2015, Part 7: 2018).

[5] The AHRI 210/240–202X Draft test procedure is available in the docket for this rulemaking at: *www.regulations.gov/document/EERE-2022-BT-TP-0028-0017*.

[6] The AHRI 1600–202X Draft test procedure is available in the docket for this rulemaking at: *www.regulations.gov/document/EERE-2022-BT-TP-0028-0018*.

[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 at page of that document).

procedure, AHRI 1600–2024, for measuring new efficiency metrics, EER, SCORE and SHORE. Appendix M2 would be 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 amending certain provisions within DOE's regulations for representation and enforcement consistent with the proposed test procedure amendments.

Table II.1 summarizes the adopted changes to the amended appendix M1 and the new appendix M2 test procedures, as well as the reason for the adopted change.

TABLE II–1—SUMMARY OF CHANGES IN AMENDED APPENDIX M1 AND NEW APPENDIX M2 TEST PROCEDURES RELATIVE TO CURRENT TEST PROCEDURE

DOE test procedure prior to amendment	Appendix M1 test procedure	Appendix M2 test procedure	Attribution
Incorporates by reference AHRI 210/240–2008.	Incorporates by reference AHRI 210/240–2024.	Incorporates by reference AHRI 1600–2024.	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 EER (same as EER2).	Updates to the applicable industry test procedures.
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 determined that the amendments to the CAC/HP test procedures in appendix M1 and newly established appendix M2 would not be unduly burdensome to conduct. Furthermore, DOE has determined that the amendments to appendix M1 would not alter the measured efficiency of CAC/HPs or require retesting or recertification solely as a result of DOE's adoption of the amendments to the test procedure. Additionally, DOE has determined that the amendments to appendix M1 would not increase the cost of testing. 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 determined, however, that new appendix M2 would 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 determined that testing according to the new appendix M2 would not increase the cost of testing as compared to appendix M1. Cost estimates are discussed in section III.J 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 amendments to representation requirements in 10 CFR 429.16 would not be required until 180 days after publication in the **Federal Register** of this final rule.

Discussion of DOE's proposed actions are addressed in further detail in section III of this final rule.

III. Discussion

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). For all central air conditioner and central air conditioning heat pump-related definitions, see appendix M or M1 of subpart B of this part. 10 CFR 430.2.

Consistent with the April 2024 NOPR, DOE is not proposing any changes to the CAC/HP definition. However, DOE notes that the last sentence in the CAC/HP definition includes references to see additional definitions in appendices M and M1. As noted in section II, in this final rule, DOE is incorporating by reference the latest industry standards, AHRI 210/240–2024 and AHRI 1600–2024, including the relevant definitions

in these standards. Therefore, references to appendices M and M1 are no longer relevant in the CAC/HP definition. To prevent confusion, DOE is removing the last sentence in the definition that contains these references. 10 CFR 430.2.

The current scope of the CACs/HP test procedure includes:

(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.

See section 1.1 of appendix M1.

DOE is not amending the scope of CACs/HPs covered by the test procedure in appendix M1 or appendix M2.

B. Updates to Industry Standards

DOE is incorporating by reference AHRI 210/240–2024 and the relevant standards it references as the basis for the updated appendix M1 test procedure. Similarly, DOE is incorporating by reference AHRI 1600–2024 and the relevant standards it references as the basis for the new appendix M2 test procedure. Incorporating each industry standard in full as the basis for each respective appendix would enable DOE to better harmonize with the industry standard and eliminate manufacturer burden in certifying with separate test procedures. The following sections discuss the referenced standards for appendices M1 and M2.

1. AHRI 210/240–2024

In the April 2024 NOPR, DOE noted that AHRI and other relevant stakeholders, including DOE, worked to develop a revised AHRI 210/240 standard, AHRI 210/240–202X Draft, that included updates to address issues pertaining to the CAC/HP test procedure with broad stakeholder consensus. 89 FR 24206, 24211–24212. DOE proposed to amend its test procedure for CAC/HPs at appendix M1 by incorporating by reference AHRI 210/240–202X Draft. *Id.* Because AHRI 210/240–202X Draft was in draft form at the time of the publication of the April 2024 NOPR, DOE noted that it intended 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. *Id.* In May 2024, AHRI published the finalized AHRI 210/240 standard, AHRI 210/240–2024, which did not include any significant deviations from AHRI 210/240–202X Draft.

AHRI, the CA IOUs, Carrier, Daikin, GE Appliances, JCI, Lennox, and NEEA were generally supportive of DOE's proposal on updating appendix M1 by adopting the finalized AHRI 210/240 standard. (AHRI, No. 25 at p. 3; Carrier, No. 29 at p. 4; CA IOUs, No. 32 at p. 1; Daikin, No. 36 at p. 1; GE Appliances, No. 37 at pp. 4–5; JCI, No. 35 at p. 1; Lennox, No. 24 at p. 3; NEEA, No. 39 at p. 2) AHRI commented that it supports the adoption of AHRI 210/240–2024 as a revised appendix M1, but with minimal additions and some exclusions, and will be publishing an addendum to AHRI 210/240–2024 that will include the aforementioned minimal additions that DOE established in the April 2024 NOPR, including revision to the definition of outdoor unit with no match. (AHRI, No. 25 at p. 3)

The Joint Advocates and CA IOUs encouraged DOE to adopt AHRI 210/240–2024 in the new CAC/HP test procedure final rule as soon as possible. (Joint Advocates, No. 30 at p. 1; CA IOUs, No. 32 at p. 1) Carrier stated that it supports the incorporation by reference of AHRI 210/240–2024 into a revised appendix M1, but with some recommendations. (Carrier, No. 29 at p. 4) Rheem commented that even though it supported the adoption of the consensus AHRI 210/240–2024 in the updated Appendix M1, it was concerned that the new versions of ANSI/ASHRAE Standard 37–2009[8] and ANSI/ASHRAE Standard 16–2016[9] with major changes, which are to be published in the near future, are not currently referenced in AHRI 210/240–2024. (Rheem, No. 34 at p. 3) Specifically, Rheem pointed out that once the new versions of the aforementioned ASHRAE standards are published, AHRI 210/240–2024 should be revised to incorporate references to the revised standards, and subsequently, DOE should update appendix M1 to incorporate the revised AHRI 210/240–2024 by reference. (*Id.* at pp. 3–4) Rheem further commented that since AHRI 210/240–2024 cites sections of 10 CFR 429.16, and of appendix M1 to subpart B of 10 CFR part 430, it should be revised to ensure that these references to CFR are still appropriate, since DOE has proposed major revisions to these sections from the CFR. (*Id.*) Rheem pointed to the newly introduced enforcement provisions in 10 CFR 429.134(k), which require calculation of average capacity (10 CFR 429.134(k)(4)(iii)(A)(*1*) and (*2*)) or time-averaged integrated (10 CFR 429.134(k)(4)(iii)(A)(*3*)) capacity and power consumption, and Rheem suggested updates to appendix I of AHRI 210/240–2024 to state that average capacity, average power consumption, time-averaged integrated capacity, and time-integrated power consumption should be calculated according to the appropriate sections of AHRI 210/240–2024 and ANSI/ASHRAE 16, as applicable. (*Id.*) Rheem pointed out that table 8 of AHRI 210/240–2024, which lists the test conditions for CAC/HPs under test, does not include the details on how to measure the compressor speed for cooling full-speed tests (A2 and B2), and cooling minimum-speed tests (B1, F1, G1, and I1) for variable-speed compressor units, as currently specified in section 3.2.4(a) of appendix M1. (*Id.* at p. 4) Rheem commented that the aforementioned details should be added as notes under table 8 of AHRI 210/240–2024, after appropriate translations of the test nomenclature.[10] *Id.*

In response to Rheem's comment, DOE notes that in the April 2024 NOPR, DOE proposed to incorporate by reference AHRI 210/240–202X draft and the AHRI 1600–202X draft, at revised appendix M1 and new appendix M2, respectively, while this final rule is updating these references to the final drafts, AHRI 210/240–2024 and AHRI 1600–2024. DOE has reviewed the finalized standards, AHRI 210/240–2024 and AHRI 1600–2024, and has concluded that all current references to 10 CFR 429.16 in the standards would

[8] ANSI/ASHRAE 37–2009 provides a method of test for many categories of air-conditioning and heating products and equipment, including CAC/HPs.

[9] ANS/ASHRAE 16–2016 provides a method of test for rating room air conditioners, packaged terminal air conditioners, and packaged terminal heat pumps.

[10] Currently, all full-speed cooling and heating mode tests in appendix M1 are identified with ''2'' in the subscript of the relevant test, whereas AHRI 210/240–202X and AHRI 1600–202X identify them with the ''Full'' subscript. Similarly, all minimum-speed cooling and heating mode tests in appendix M1 are identified with ''1'' in the subscript of the relevant test, whereas AHRI 210/240–202X and AHRI 1600–202X identify them with the ''Low'' subscript.

not require revision. Additionally, DOE clarifies that any further updates to appendix I of the AHRI 210/240 and AHRI 1600 standards to add the definitions of average capacity, average power consumption, time-averaged integrated capacity, and time-integrated power consumption will have to be initiated by AHRI, as part of an addendum. DOE has determined that additional definitions are not necessary at this time and notes that an updated appendix I to AHRI 210/240 and AHRI 1600 is not yet available for review; therefore, DOE is not adopting additional definitions as recommended by Rheem at this time. Regarding Rheem's comment on table 8 of AHRI 210/240–2024 lacking language from section 3.2.4 (a) of the current appendix M1 for maintaining the same full compressor speed for all full-speed cooling tests, and the same minimum compressor speed for all minimum-speed cooling tests, DOE is adding provisions in section 2 of the revised appendix M1 and section 2 of the new appendix M2, consistent with the existing requirement in appendix M1, as follows:

For cooling mode tests of variable capacity systems, the compressor shall operate at the same cooling full speed, measured by RPM of power input frequency (Hz), for both A_{Full} and B_{Full} tests. Additionally, the compressor shall operate at the same cooling minimum speed, measured by RPM or power input frequency (Hz), for the B_{Low}, F_{Low}, G_{Low}, and I_{Low} tests.

As noted, in May 2024, AHRI published AHRI 210/240–2024, which does not include any significant deviations from AHRI 210/240–202X Draft. As such, the adoption of AHRI 210/240–2024 in this final rule is consistent with the proposal to reference AHRI 210/240–202X Draft in the April 2024 NOPR.

Therefore, DOE is amending its test procedure for CAC/HPs by incorporating by reference AHRI 210/240–2024 for use in the new appendix M1. Specifically, in the new test procedure for CAC/HPs at appendix M1, DOE is adopting sections 3 (excluding 3.2.16, 3.2.20, 3.2.46, 3.2.51, 3.2.63, 3.2.78 and 3.2.79), 5 (excluding 5.1.6.2), 6.1–6.3, and 6.6, and Appendices D, E, G, and K of AHRI 210/240–2024.[11]

Additionally, as proposed in the April 2024 NOPR, DOE is making additions and deletions to the incorporations by reference for the CAC/HP Federal test procedure (*see* 10 CFR 430.3) to align with the references made within AHRI 210/240–2024. 89 FR 24206, 24212.

Currently, appendix M1 incorporates by reference: AMCA 210–2007,[12] AHRI 210/240–2008, AHRI 1230–2010,[13] ASHRAE 23.1–2010,[14] ANSI/ASHRAE 37–2009, and ASHRAE 116–2010. 10 CFR 430.3.

In the amended test procedure at appendix M1, DOE is adding an incorporation by reference to ANSI/ASHRAE 16–2016 and removing incorporations by reference to AMCA 210–2007, AHRI 210/240–2008, AHRI 1230–2010, and ASHRAE 23.1–2010. Therefore, DOE is incorporating by reference AHRI 210/240–2024, ANSI/ASHRAE 16–2016, ANSI/ASHRAE 37–2009, and ANSI/ASHRAE 116–2010, at appendix M1.

2. AHRI 1600–2024

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).

In the April 2024 NOPR, DOE proposed to establish a new test procedure for CAC/HPs at appendix M2 by incorporating by reference AHRI 1600–202X Draft (in its entirety). 89 FR 24206, 24212. DOE noted that it intended 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. *Id.* In May 2024, AHRI published the finalized AHRI 1600 standard, AHRI 1600–2024, which did not include any significant deviations from AHRI 1600–202X Draft.

Several stakeholders, namely Lennox, AHRI, Mitsubishi, Copeland, the CA IOUs, Rheem, Daikin, NEEA, and Carrier, appreciated DOE's efforts of collaborating with the stakeholders to develop the AHRI 1600 standard, and supported its adoption at appendix M2. (Lennox, No. 24 at p. 4; AHRI, No. 25 at p. 3;[15] Mitsubishi, No. 28 at p. 1; Copeland, No. 31 at p. 1; CA IOUs, No. 32 at p. 2; Rheem, No. 34 at p. 4; Daikin, No. 36 at p. 1; NEEA, No. 39 at p. 2; Carrier, No. 29 at p. 4) Rheem commented that in a similar vein to its comment made on AHRI 210/240–2024 (*see* section III.B.1 of this document), DOE should be aware that the revised editions of ANSI/ASHRAE Standard 37 and ANSI/ASHRAE Standard 16 are currently not referenced in AHRI Standard 1600–2024. (Rheem, No. 34 at p. 4) Rheem further pointed to DOE's inclusion of the energy efficiency metric energy efficiency ratio 2 (''EER2) in 10 CFR 430.23(m)(2); several sections of 10 CFR 429.16 and 10 CFR 429.134(k)(4); and sections 2, 4.1, and 4.2 of appendix M2 to subpart B of 10 CFR part 430, which in turn incorporate AHRI 1600–2024 by reference, which only includes energy efficiency ratio (''EER'') as the efficiency metric, and not EER2. (*Id.* at p. 5) Rheem stated that this mismatch should be resolved by either DOE revising its relevant references from EER2 to EER, or that AHRI 1600–2024 should be revised to replace all instances of EER with EER2. (*Id.*) Further, Rheem pointed out that section 4.1 of the new appendix M2 references 10 CFR 431.97, in relation to certification to the energy conservation standards SCORE and SHORE, and suggested this citation should be changed to 10 CFR 430.32(c), which will be amended to prescribe energy conservation standards for CAC/HPs. (*Id.*) Additionally, as noted in section III.B.1 for AHRI 210/240–2024, Rheem commented that table 8 of AHRI 1600–2024 should contain sentences similar to section 3.2.4(a) of appendix M1, to

[11] DOE notes that the substance of these provisions remains the same as those proposed in the April 2024 NOPR, but AHRI did some reorganization in moving from AHRI 210/240–202X Draft to AHRI 210/240–2024. Consequently, the adopted section numbers cited here differ from those presented in DOE's proposed rule. *See* 89 FR 24206, 24212.

[12] 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*.

[13] 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*.

[14] 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.*

[15] While AHRI's comment noted support for the adoption of the AHRI 1600 standard at appendix M1, DOE surmises that this is a typographical error, and AHRI intended to express support for adoption at appendix M2 instead. As proposed in the April 2024 NOPR, appendix M1 references the draft AHRI 210/240 standard.

specify that for variable-speed compressor systems, the cooling full compressor speed for both A2 and B2 tests should be same, and the cooling minimum compressor speed for the B1, F1, G1, and I1 tests should remain the same. (*Id.* at p. 4)

In response to Rheem's comment regarding AHRI 210/240–2024 retaining the EER2 metric while AHRI 1600–2024 using the EER metric, DOE agrees with Rheem that this mismatch has potential to confuse users of the test procedure. DOE notes that the EER2 metric in AHRI 210/240–2024 is identical to the EER metric in AHRI 1600–2024. Both metrics are evaluated at the same test conditions and convey the same full-load efficiency information. Therefore, for appendix M1, which references AHRI 210/240–2024, DOE is retaining the EER2 metric. For appendix M2, which references AHRI 1600–2024, DOE is including EER as the full-load metric, with EER evaluated the same way as EER2 per appendix M1. DOE is making appropriates changes in the regulatory text at 10 CFR parts 429 and 430, and appendix M2, to reflect this clarification. In response to Rheem's comment for the citation of the SCORE and SHORE energy conservation standards in the April 2024 NOPR, DOE agrees that the correct citation is to 10 CFR 430.32(c), and not 10 CFR 431.97. Finally, as mentioned in section III.B.1 of this document, DOE is adding language to section 2 of appendix M2 to explicitly state that for variable-capacity compressor systems, the cooling full compressor speeds for both A_{Full} and B_{Full} tests should be identical, and the cooling minimum compressor speed for the B_{Low}, F_{Low}, G_{Low}, and I_{Low} tests should be identical.

As discussed, AHRI 1600–2024 does not include any significant deviations from AHRI 1600–202X Draft. As such, the adoption of AHRI 1600–2024 in this final rule is consistent with the proposal to reference AHRI 1600–202X Draft in the April 2024 NOPR.

DOE is amending its test procedure for CAC/HPs by incorporating by reference AHRI 1600–2024 for use in the new appendix M2. Specifically, in the new test procedure for CAC/HPs at appendix M2, DOE is adopting sections 3 (excluding 3.2.16, 3.2.20, 3.2.45, 3.2.50, 3.2.63, 3.2.78, and 3.2.79), 5 (excluding 5.1.6.2), 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.

Additionally, consistent with the April 2024 NOPR, DOE is also incorporating by reference ANSI/ASHRAE 16–2016, ANSI/ASHRAE 37–2009, and ANSI/ASHRAE 116–2010, which are referenced within AHRI 1600–2024. Therefore, in total, DOE is proposing to incorporate by reference AHRI 1600–2024, ANSI/ASHRAE 16–2016, ANSI/ASHRAE 37–2009, and ANSI/ASHRAE 116–2010, at appendix M2.

3. ANSI/ASHRAE 37–2009

ANSI/ASHRAE 37–2009 provides a method of test for electrically driven unitary air-conditioning and heat pump equipment, which includes CAC/HPs. In the April 2024 NOPR, DOE proposed to incorporate by reference ANSI/ASHRAE 37–2009 at both appendix M1 and appendix M2, since AHRI 210/240–202X Draft and AHRI 1600–202X Draft both reference test instructions in ANSI/ASHRAE 37–2009. 89 FR 24206, 24212. The finalized versions of these draft standards, AHRI 210/240–2024 and the AHRI 1600–2024, also reference ANSI/ASHRAE 37–2009. More specifically, sections 5, 6, 8, and 11 and appendices C, D, E, I, and J of AHRI 210/240–2024 and AHRI 1600–2024 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 210/240–2024 Draft references ANSI/ASHRAE 37–2009 for several test instructions, DOE has concluded, consistent with the April 2024 NOPR, that it is appropriate to maintain the existing incorporation by reference of ANSI/ASHRAE 37–2009 in appendix M1. Additionally, given that AHRI 1600–2024 references ANSI/ASHRAE 37–2009 for several test instructions, DOE has concluded, consistent with the April 2024 NOPR, that it is appropriate to 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 the AHRI 210/240–202X Draft and the AHRI 1600–202X Draft. Consequently, in the April 2024 NOPR, DOE proposed to incorporate by reference ANSI/ASHRAE 16–2016 at both appendix M1 and appendix M2. 89 FR 24206, 24213. The finalized versions of the AHRI draft standards, AHRI 210/240–2024 and AHRI 1600–2024, also reference ANSI/ASHRAE 16–2016. More specifically, section 5.1.1 of AHRI 210/240–2024 and AHRI 1600–2024 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 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 AHRI 210/240–2024 and AHRI 1600–2024 refer to ANSI/ASHRAE 16–2016 as an option for testing of non-ducted CAC/HPs, and it does not impact ratings, DOE has concluded, consistent with the April 2024 NOPR, 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. Consequently, in the April 2024 NOPR, DOE proposed to incorporate by reference ANSI/ASHRAE 116–2010 at both appendix M1 and appendix M2. 89 FR 24206, 24213. The finalized versions of the AHRI draft standards, AHRI 210/240–2024 and AHRI 1600–2024, also reference ANSI/ASHRAE 116–2010. More specifically, sections 5, 6, 8, and 11 and appendices D and E of AHRI 210/240–2024 and AHRI 1600–2024 refer to methods of test in ANSI/ASHRAE 116–2010.

Given that AHRI 210/240–2024 references ANSI/ASHRAE 116–2010 for several test instructions, DOE has concluded, consistent with the April 2024 NOPR, that it is appropriate to maintain the incorporation by reference of ANSI/ASHRAE 116–2010 in appendix M1. Additionally, given that the AHRI 1600–2024 Draft references ANSI/ASHRAE 116–2010 for several test instructions, DOE has concluded, consistent with the April 2024 NOPR, that it is appropriate to incorporate by reference ANSI/ASHRAE 116–2010 for use with appendix M2.

C. Revised 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)(3))

In this final rule, DOE is maintaining the current efficiency metrics, EER2, SEER2 and HSPF2, at appendix M1 and is referencing AHRI 210/240–2024 for measuring the existing metrics. DOE has determined that the amendments to appendix M1 would not affect the measured efficiency of CAC/HPs or require retesting solely because of DOE's adoption of the amendments to the appendix M1 test procedure. At appendix M1, DOE is incorporating by reference the following sections of the AHRI 210/240–2024: sections 3 (with certain exclusions [16]), 5 (with one exclusion [17]), 6 (with certain exclusions [18]), 11, and 12, as well as appendices D, E, G, K, and L.

Additionally, DOE is establishing a new test procedure at appendix M2 that adopts AHRI 1600–2024, including the new SCORE and SHORE metrics.[19] Use of appendix M2 is not required until the compliance date of any amended standards denominated in terms of the new metrics for appendix M2, should such standards be adopted. At appendix M2, DOE is referencing the following sections of AHRI 1600–2024: sections 3 (with certain exclusions [20]), 5 (with one exclusion [21]), 6 (with certain exclusions [22]), 11, and 12 and appendices D, E, G, K and L.

Further, at both appendix M1 and appendix M2, DOE is incorporating by reference the following: ANSI/ASHRAE 37–2009, except sections 1 (Purpose), 2 (Scope), and 4 (Classifications); ANSI/ASHRAE 16–2016 except sections 1 (Purpose), 2 (Scope), and 4 (Classifications); and ANSI/ASHRAE 116–2010 except sections 1 (Purpose), 2 (Scope), 4 (Classifications), and 7 (Methods of Test).

D. Efficiency Metrics

As discussed, DOE is updating 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 210/240–2024. DOE is also establishing a new Federal test procedure at 10 CFR part 430, subpart B, appendix M2, consistent with the new industry consensus test procedure, AHRI 1600–2024. Sections III.D.1 and III.D.2 of this document discuss which metrics are applicable for appendices M1 and M2, respectively.

1. Metrics Applicable to Appendix M1

Consistent with the April 2024 NOPR, appendix M1 maintains the current energy efficiency metrics (*i.e.,* EER2, SEER2, and HSPF2), and includes a new optional metric: the peak load coefficient of performance (''COP_{peak}''), applicable to central heat pumps (''CHPs''). The amendments to appendix M1 to align with AHRI 210/240–2024 maintain the existing energy efficiency metrics, and DOE has determined that testing under 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

The newly established appendix M2 introduces 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 integrated metrics that include off mode power, $P_{W,OFF}$. Hence, appendix M2 will not require separate representations for off mode power. Appendix M2 will retain the full-load EER metric, with EER evaluated in the same way as appendix M1.[23] Appendix M2 also includes the optional metric COP_{peak}.

E. 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 required 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 210/240–2024. DOE has reviewed AHRI 210/240–2024 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)(3)) These near-term amendments in appendix M1 do not alter the measured efficiency of CAC/HPs in terms of the current cooling and heating test metrics, SEER2 and HSPF2, or the current off mode metric, $P_{W,OFF}$.

DOE clarifies that while all issues discussed subsequently within this section are near-term, they are also part of the long-term CAC/HP test procedure—*i.e.,* these revisions are also included in AHRI 1600–2024, which DOE is incorporating by reference at appendix M2. As such, when discussing these near-term changes, DOE makes references to both AHRI 210/240–2024 and AHRI 1600–2024.

1. Controls Verification Procedure for Variable-Speed Systems

Appendix M1 uses a steady-state test concept for variable-speed systems 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 a fixed specified compressor speed and airflow rate for each test point. As part of the previous rulemaking, several stakeholders encouraged DOE to review ways to improve the representativeness of the test procedures for CAC/HPs (especially variable-speed systems), particularly to consider test procedures where the unit operates under its own native controls in responding to conditioning loads (*i.e.,* load-based testing).[24]

[16] DOE is not incorporating by reference the following provisions in section 3 of AHRI 210/240–2024 because the terms are either defined in appendix M1, or are not needed for the DOE test procedure: 3.2.16 (Double-duct System), 3.2.20 (Gross Capacity), 3.2.46 (Oil Recovery Mode), 3.2.51 (Published Rating), 3.2.63 (Standard Filter), 3.2.78 (Unitary Air-conditioner), and 3.2.79 (Unitary Heat Pump).

[17] DOE is not incorporating by reference the following provision in section 5 of AHRI 210/240–2024 because the term is defined in appendix M1: 5.1.6.2 (Outdoor Unit with No Match (OUWNM)).

[18] DOE is not incorporating by reference the following provisions in section 6 of AHRI 210/240–2024 because the provisions are either defined in 10 CFR 429.16, or are not needed for the 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).

[19] As explained in Section III.B.2, DOE will replace EER2 in appendix M1 with EER in appendix M2. However, EER will be calculated in a manner identical to EER2, and both convey the same full load test information.

[20] DOE is not incorporating by reference the following provisions in section 3 of AHRI 1600–2024 because the terms are either defined in appendix M1, or are not needed for the DOE test procedure: 3.2.16 (Double-duct System), 3.2.20 (Gross Capacity), 3.2.45 (Oil Recovery Mode), 3.2.50 (Published Rating), 3.2.63 (Standard Filter), 3.2.78 (Unitary Air-conditioner), and 3.2.79 (Unitary Heat Pump).

[21] DOE is not incorporating by reference the following provision in section 5 of AHRI 1600–2024 because the term is defined in appendix M2: 5.1.6.2 (Outdoor Unit with No Match (OUWNM)).

[22] DOE is not incorporating by reference the following provisions in section 6 of AHRI 1600–2024 D because the provisions are either defined in 10 CFR 429.16, or are not needed for the 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).

[23] AHRI 1600–2024 replaced the EER2 and COP2 metrics from AHRI 210/240–2024 with EER and COP. For consistency, appendix M2 will follow the nomenclature in AHRI 1600–2024 and will hence use EER as the full-load metric, while appendix M1 will use the EER2 metric.

[24] 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

Continued

To review this topic in detail as part of the current rulemaking, in an RFI published on January 24, 2023, (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.

In the April 2024 NOPR, 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 load-based testing methods have sufficient repeatability and reproducibility to be the basis of direct measurement of system performance—DOE tentatively concluded that use for direct measurement of performance for regulatory purposes would not be suitable at this time. 89 FR 24206, 24220. Instead, DOE tentatively concluded that it would be appropriate to continue to allow regulatory tests to use fixed-speed settings for testing variable-speed systems, while developing a controls verification procedure (''CVP'') that could be used for audit, assessment, and enforcement testing to ensure that the fixed-speed settings are representative of native (unfixed) control, in which the control system may vary compressor speed and/or indoor airflow. *Id.*

DOE noted that AHRI and other relevant stakeholders, including DOE, participated in the development of revised AHRI test standards to address several issues raised in the January 2023 RFI, including the representativeness of fixed-speed testing for variable-speed systems. 89 FR 24206, 24220. From these discussions on the revised AHRI test standards, consensus was developed on using a CVP approach. *Id.* In section III.F.1.e of the April 2024 NOPR, DOE provided a summary of the CVP approach in Appendix I of AHRI 210/240–202X Draft and AHRI 1600–202X Draft. 89 FR 24206, 24220–24222.

DOE acknowledged that the CVP approach outlined in appendix I of the relevant AHRI drafts represented industry consensus regarding: (1) the verification of compliance of systems with the variable capacity system definition, and (2) verification of the consistency of fixed-speed settings of compressor and indoor fans with native control operation as part of enforcement. 89 FR 24206, 24222. DOE considered that the CVP approach presented a more representative test procedure for variable-speed systems operating in the field, because it provided a tool to verify that the fixed 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 set point, *i.e.,* indoor dry-bulb temperature. *Id.* For these reasons, DOE proposed to incorporate by reference appendix I of 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 AHRI 1600–202X Draft to support enforcement associated with testing conducted in accordance with appendix M2. *Id.*

In response to DOE's proposal, several stakeholders, namely Lennox, the CA IOUs, Rheem, Daikin, GE Appliances, and Carrier, generally showed support for DOE's proposal on implementing the CVP approach for certification of variable-speed products. (Lennox, No. 24 at p. 2; CA IOUs, No. 32 at p. 2; Rheem, No. 34 at p. 5; Daikin, No. 36 at p. 3; GE Appliances, No. 37 at p. 4; Carrier, No. 29 at p. 5)

The Joint Advocates commented that even though it is not appropriate to adopt load-based testing for measuring the direct regulatory test performance of CAC/HPs due to insufficient information on repeatability and reproducibility of load-based testing methods, DOE should consider adopting them as an integral part of the test procedure in a future update to the CAC/HP test procedure. (Joint Advocates, No. 30 at pp. 3–4) Further, the Joint Advocates commented that test data that will better inform repeatability and reproducibility of load-based tests will be coming out in the near future. (*Id.*) The Joint Advocates expressed concern that since the CVP is only an enforcement provision, manufacturers are not required to conduct it while rating their product, and hence, adopting some version of load-based testing will ensure that all certified ratings are more representative of unit performance in the field. (*Id.*)

In response to the Joint Advocates' comment, DOE reiterates that it explored the potential of adopting a load-based method for direct measurement of performance in the April 2024 NOPR. However, as discussed in the April 2024 NOPR, the consensus of affected stakeholders was to adopt a CVP approach instead of a wholesale load-based method test procedure. 89 FR 24206, 24222. DOE is not aware of additional information, such as new load-based test data, available for review to assess the feasibility of adopting load-based testing as a mandatory part of the CAC/HP test procedure. Even though the CVP is primarily intended for use by DOE for assessment and enforcement purposes, it is expected that manufacturers will preemptively utilize the CVP to evaluate the fixed-speed settings used for certification tests of their variable-speed products to ensure consistency with native-control operation.

AHRI 210/240–2024 and AHRI 1600–2024, the industry standards DOE is referencing in this final rule, finalized the relevant test method for the CVP at appendix I without any substantial change as compared to their corresponding drafts. Therefore, consistent with the April 2024 NOPR, DOE is incorporating by reference appendix I of AHRI 210/240–2024 to support enforcement associated with testing conducted in accordance with appendix M1, and to incorporate by reference appendix I of AHRI 1600–2024 to support enforcement associated with testing conducted in accordance with appendix M2. The enforcement provisions are discussed in more detail in section III.I.2 of this document.

2. Low-Temperature Heating Performance

In the April 2024 NOPR, DOE proposed to incorporate by reference AHRI 210/240–202X and AHRI 1600–202X Drafts and adopt several test procedure provisions that pertained to low-temperature heating performance. 89 FR 24206, 24222–24225. Specifically, DOE proposed to (1) reference the definition of ''cold climate heat pump'' (''CCHP'') contained in the AHRI drafts, (2) reference the requirement for products certified as a CCHP to conduct the H4 heating test (either the H4, $H4_{Full}$, or $H4_{Boost}$ heating test, as applicable), (3) retain the current size-for-cooling approach, and (4) include COP_{peak} as an optional representation for combined heat pump and electric resistance heat efficiency at 5 °F outdoor temperature for CHPs, as outlined in appendix K of AHRI 210/240–202X and AHRI 1600–202X Drafts,[25] at appendix M1 and appendix M2, respectively.

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.

[25] In several instances of the April 2024 NOPR, DOE incorrectly referred to appendix L of the

DOE did not receive any comments regarding the aforementioned proposals in the April 2024 NOPR. AHRI 210/240–2024 and AHRI 1600–2024, the final versions of the draft AHRI standards, finalized the same low-temperature heating performance provisions without change. Therefore, consistent with the April 2024 NOPR proposal, DOE is incorporating by reference AHRI 210/240–2024 and AHRI 1600–2024 and adopting the low-temperature heating performance provisions discussed in the aforementioned paragraphs.

3. Cut-Out and Cut-In Temperature Verification

Appendix J of AHRI 210/240–202X Draft and also of AHRI 1600–202X Draft includes a test applicable to all CHPs to determine cut-out and cut-in temperatures (*i.e.,* T_{off} and T_{on} respectively).[26] In the April 2024 NOPR, DOE proposed that during assessment and enforcement testing of CHPs, DOE may verify the cut-out and cut-in temperatures using the test specified in appendix J of AHRI 210/240–202X Draft, when conducting assessment and enforcement testing associated with appendix M1, and the test specified in appendix J of AHRI 1600–202X Draft, when conducting assessment and enforcement testing associated with appendix M2. The proposal indicated that, if conducting the appendix J cut-out/cut-in verification, the tested values determined for these temperatures would be used as the T_{off} and T_{on} values for the unit. 89 FR 24206, 24226.

AHRI 210/240–2024 and AHRI 1600–2024, the industry standards DOE is referencing in this final rule, finalized the relevant test method for determining cut-out and cut-in temperatures at appendix J without any substantial change as compared to their respective drafts. Therefore, consistent with the April 2024 NOPR, DOE is incorporating by reference appendix J of AHRI 210/240–2024 and AHRI 1600–2024 at appendix M1 and appendix M2, respectively.

As further discussed in section III.I.1 of this document, DOE may verify certified cut-out and cut-in temperatures using the test methods in appendix J 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 external static pressure (''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 inches of water column (''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.

AHRI 210/240–202X Draft and AHRI 1600–202X Draft 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 Specified 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 Specified with a blower-coil indoor unit tested with a minimum 0.5 in H2O ESP, otherwise it is separately Specified with a coil-only indoor unit; and

(3) The Indoor Unit is marketed for and produces a maximum ESP less than 0.5 in H2O when operated at the Specified cooling full-load airflow not exceeding 400 scfm per Specified ton of cooling.

Both drafts also include provisions requiring low-static single-split blower-coil systems to be tested at their specified airflow (not to exceed 400 standardized cubic feet per minute (''scfm'') per specified ton of cooling capacity) at their maximum airflow setting. If the ESP achieved at the specified airflow is less than 0.1 in. wc., the provisions require adjustment of the airflow measurement apparatus fan to reduce airflow and increase ESP until a minimum of 0.1 in. wc. is achieved.

In the April 2024 NOPR, DOE proposed to incorporate by reference the new definition of low-static single-split blower-coil system and associated testing provisions, which would include single-split systems that cannot accommodate the 0.5 in. wc. required for testing single-split blower-coil systems in accordance with the current DOE test procedure in appendix M1. 89 FR 24206, 24227.

DOE did not receive any comments regarding the aforementioned proposals in the April 2024 NOPR. AHRI 210/240–2024 and AHRI 1600–2024 finalized the definition and testing provisions for low-static single-split blower-coil systems without substantial change as compared with their respective drafts. Therefore, consistent with the April 2024 NOPR proposals, DOE is incorporating by reference AHRI 210/240–2024 and AHRI 1600–2024, and adopting the definition and testing provisions for low-static single-split blower-coil systems.

In advance of adopting these changes, multiple manufacturers, including Samsung HVAC America LLC (''Samsung''),[27] Mitsubishi,[28] and Hisense (Guangdong) Air Conditioning Co. Ltd. (''Hisense''),[29] petitioned DOE for test procedure waivers pertaining to low-static single-split blower-coil systems. All petitions asserted nearly identical circumstances and model limitations—that it was impossible to test certain basic models according to appendix M1 because the models could not operate at the conventional minimum ESP requirement of 0.5 in. wc. found in table 4 of appendix M1. Subsequently, manufacturers could not certify compliance for or sell these products.

On June 5, 2023, DOE published a notification of petition for waiver and grant of an interim waiver that permits Samsung to use an alternative test procedure for the basic models subject to its petition. 88 FR 36558. The alternative test procedure allows Samsung to test its basic models that are designed for low-static, short-duct applications at 0.1 in. wc. ESP and to make proportional adjustments to fan power and capacity such that the results are equivalent to performance measured at 0.5 in. wc. ESP. 88 FR 36558, 36561–36563. DOE initially determined that this alternate test procedure was appropriate and allowed for the accurate measurement of the energy efficiency of the specified basic models, while alleviating the testing problems cited in implementing the DOE test procedure for the models. *Id.*

In the April 2024 NOPR, DOE noted that, should the new definition of low-

respective AHRI 210/240–202X and AHRI 1600–202X Drafts as the appendices regarding COP_{peak}. (*See* 89 FR 24206, 24225). These were typographical errors, since the appendices regarding COP_{peak} are at appendix K of the respective AHRI 210/240–202X and AHRI 1600–202X Drafts.

[26] In several instances of the April 2024 NOPR, DOE incorrectly referred to appendix K of the respective AHRI 210/240–202X and AHRI 1600–202X Drafts as the appendices regarding cut-out and cut-in temperature verification. (*See* 89 FR 24206, 24226 and 89 FR 24206, 24243). These were typographical errors, since the appendices regarding cut-out and cut-in temperature verification are at appendix J of the respective AHRI 210/240–202X and AHRI 1600–202X Drafts.

[27] *See* Samsung's petition at *www.regulations.gov/docket/EERE-2023-BT-WAV-0010.*

[28] *See* Mitsubishi's petition at *www.regulations.gov/docket/EERE-2023-BT-WAV-0015.*

[29] *See* Hisense's petition at *www.regulations.gov/docket/EERE-2023-BT-WAV-0011.*

static single-split blower-coil system and the associated testing provisions be adopted, DOE would terminate Samsung's interim waiver pending final determination. 89 FR 24206, 24227. The interim waiver was granted with the understanding that it was impossible to test the manufacturer's specific basic models according to the prescribed test procedures in appendix M1. Given that DOE is adopting provisions for low-static single-split blower-coil systems, DOE concludes that this alternate test procedure is no longer necessary. Therefore, DOE is terminating the aforementioned waiver for Samsung. DOE notes that the ratings for the subject Samsung basic models may change when moving to the amended appendix M1 test procedure outlined in this final rule.

DOE has not published a notification of petition for waiver or granted interim waivers for either the Mitsubishi or Hisense petitions. However, for the same reasons that DOE is terminating Samsung's aforementioned waiver, DOE concludes that an alternate test procedure is no longer necessary. DOE considers the petitions submitted by Mitsubishi and Hisense to be addressed sufficiently by the low-static single-split blower-coil system definition and testing provisions adopted in this final rule.

5. Mandatory Constant Circulation Systems

Currently, nearly all CAC/HP products are designed with R–410A as the refrigerant. However, under global warming potential (''GWP'') restrictions enacted by an Environmental Protection Agency (''EPA'') final rule published on October 24, 2023 (''October 2023 EPA final rule''), the use of R–410A is scheduled to be phased out for CAC/HP products.[30] 88 FR 73098. The EPA Significant New Alternatives Policy (''SNAP'') Program evaluates and regulates substitutes for ozone-depleting chemicals (such as CAC/HP refrigerants) that are being phased out under the stratospheric ozone protection provisions of the Clean Air Act. (42 U.S.C. 7401 *et seq.*) [31] Of interest to CAC/HPs, the EPA SNAP Program's list of viable substitutes [32] includes a group of refrigerants classified as A2L refrigerants. While these refrigerants have GWP levels meeting the requirements of the October 2023 EPA Final Rule, they face stricter safety requirements than R–410A due to the moderate flammability associated with their ''2L'' ASHRAE safety classification.[33] Many of the safety requirements specifically address mitigation of ignition risk in case of refrigerant leakage. One mitigation option for refrigerant leakage is air circulation, which can be initiated when a leak is detected, or the system can use ''constant circulation,'' running the fan, typically at a reduced speed, at all times. This latter approach has energy use implications, which are addressed in the AHRI 210/240 and AHRI 1600 standards.[34]

AHRI 210/240–202X Draft and AHRI 1600–202X Draft include a new definition for ''mandatory constant circulation system'' (''MCCS''). The updated industry standard drafts also include testing provisions for such systems, specifically requiring that CAC/HPs meeting the mandatory constant circulation system definition not use the default cooling and heating degradation coefficients, but rather evaluate these degradation coefficients using the respective cyclic tests specified by table 7 of AHRI 210/240–202X Draft and AHRI 1600–202X Draft, conducted in accordance with section E12 of appendix E of AHRI 210/240–202X Draft and AHRI 1600–202X Draft. In the April 2024 NOPR, DOE proposed to incorporate by reference the new definition of MCCS and the aforementioned testing provisions outlined in AHRI 210/240–202X Draft and AHRI 1600–202X Draft, at appendix M1 and appendix M2, respectively. 89 FR 24206, 24228.

In response to DOE's proposal, Carrier expressed support for the MCCS testing approach, but it commented that there is ambiguity regarding the specific products to which the MCCS testing approach applies. (Carrier, No. 29 at pp. 2–3) Carrier stated that for a CAC/HP system with a charge quantity between m1 and m2,[35] the room size in which the UL 60335–2–40 4th edition refrigerant safety standard allows the system to be installed (or the effective volume into which refrigerant would be dispersed in case of leakage) is limited. Further, this limitation can be stricter if the system does not employ air circulation, either continuously or initiated by a refrigerant leak detection system (''LDS''). (*Id.*) Carrier requested that DOE provide further specificity on the testing approach for products that might require air circulation as mitigation in some installations but not necessarily all installations. (*Id.*) Carrier recommended that DOE require all systems with a charge level greater than m1 and less than or equal to m2 that do not contain an LDS be tested as an MCCS since how and where these products are installed in the field are outside the manufacturer's control (besides a label specifying the required area). (*Id.*)

In a rebuttal, Daikin opposed Carrier's aforementioned recommendation, for several reasons. (Daikin, No. 40 at p. 1) First, Daikin commented that UL 60335–2–40 4th edition is clear in its requirements for information that must be provided in installation instructions, including instructions regarding how to install the product in accordance with refrigerant safety codes, including how to meet the minimum floor area requirements. (*Id.*) Daikin specifically pointed to Annex DD of UL 60335–2–40 4th edition, which specifies that an original equipment manufacturer (''OEM'') must include details of minimum installation height, minimum floor area, and other appropriate information in installation instructions to ensure safety requirements are met. (*Id.*) Daikin also commented that CAC/HPs using A2L refrigerant, in addition to providing information in installation instructions, must have adequate warning labels (per Clause 7 of UL 60335–2–40 4th edition, Annex 101.DVF of UL 60335–2–40 4th edition, and EPA SNAP Rule 25), such that the installer will be well aware the product being installed needs special attention. (*Id.*)

Second, Daikin commented that the minimum floor area required by ASHRAE 15.2 (with which UL 60335–2–40 requires compliance), for some situations, does not depend on whether

[30] EPA published an interim final rule on December 26, 2023 (''EPA Technology Transition Interim Final Rule'') that allows 1 additional year, until January 1, 2026, solely for the installation of new CAC/HPs using components manufactured or imported prior to January 1, 2025. 88 FR 88825.

[31] Additional information regarding EPA's SNAP Program is available online at *www.epa.gov/ozone/snap/*.

[32] A 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*.

[33] 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).

[34] DOE is aware that a refrigerant leakage detection system may also draw power, which would also be addressed in the AHRI 210/240 and AHRI 1600 test standards. However it is DOE's understanding that the impact of this power is much less than operation of the fan in constant circulation mode.

[35] UL 60335–2–40 fourth edition defines charge quantities m1 and m2 based on the type of refrigerant.

the system employs circulation (whether continuous or LDS initiated) to meet mitigation requirements. (Daikin, No. 40 at p. 2)

Third, Daikin commented that, if a manufacturer chooses to use continuous circulation airflow as the method of leak mitigation, the manufacturer must conduct additional safety verification of that function, per Annex GG of UL 60335–2–40 4th edition (specifically, Clause GG.2.2.2DV). (Daikin, No. 40 at pp. 2–3) Annex GG of UL 60335–2–40 4th edition states that a product using continuous circulation shall (1) run the indoor fan continuously, except for short periods of maintenance and service; (2) detect or monitor continuously if the airflow rate drops below a specific level (Q_{min}); and (3) if the airflow drops below the specified level, provide an output signal that airflow is reduced and disable compressor operation unless the compressor operation reduces the leak rate or the total amount of refrigerant released to the indoor space. Consequently, Daikin commented that, if the manufacturer chooses to rely on continuous circulation as the mitigation method, the OSHA-certified Nationally Recognized Testing Laboratory (''NRTL'') that certifies the product to meet the safety standard UL 60335–2–40 must check by inspection that the manufacturer runs the fan continuously. (*Id.*)

Fourth, Daikin commented on the DOE test procedure emphasis on installation instructions. (Daikin, No. 40 at p. 3) The DOE test procedure requirement to follow the OEM installation instructions when installing a system for testing is based on the premise that the installation instructions provide a setup representative of field installation. Thus, Daikin asserted it would be logical for DOE to be consistent and also assume that the installing contractor would follow requirements related to refrigerant safety that are laid out in installation instructions. (*Id.*)

In response to the Carrier and Daikin comments, it is DOE's understanding (as noted in Daikin's comment) that use of constant circulation as the method of refrigerant leakage risk mitigation requires that the CAC/HP product must be inherently designed with this feature—a contractor cannot be in compliance with UL 60335–2–40 4th edition requirements if the feature is selected in the field for a system that does not inherently already have it. Specifically, an NRTL must certify upon inspection that a product using constant circulation for safety code compliance indeed runs its indoor fan continuously. Thus, the circumstances ''outside the manufacturer's control'' involving installation by a contractor using constant circulation as the means of mitigation of systems without LDS and without MCCS that Carrier mentioned in its comment are violations of refrigerant safety codes. While such violations may occur in the future, DOE concludes that the seriousness of the potential consequences would make them infrequent, *i.e.,* such circumstances could not be considered representative of the installation of such systems. Therefore, DOE determines that, for testing according to the DOE test procedure, it is not appropriate to require testing using constant circulation for products with charge between m1 and m2 that don't have an LDS and are not inherently an MCCS. However, any product using constant circulation to comply with refrigerant safety codes that would meet the MCCS definition in AHRI 210/240–202X Draft and AHRI 1600–202X Draft could be verified to have this status by powering up the unit, and consequently will be required to test as an MCCS.

AHRI 210/240–2024 and AHRI 1600–2024 finalized the definition and testing provisions for MCCS without substantial change. DOE has determined that the definition and approach included in the finalized versions provide a more representative measure of CAC/HP efficiency for systems utilizing mandatory constant circulation as a means of refrigerant leakage mitigation. Therefore, consistent with the April 2024 NOPR proposals, DOE is incorporating by reference AHRI 210/240–2024 and AHRI 1600–2024 and adopting the definition and testing provisions for MCCS.

Daikin noted in its comment that the certification aspects of the MCCS test procedure changes were not included in the April 2024 NOPR. (Daikin, No. 40 at p. 3) Daikin recommended that DOE include as mandatory certification a declaration from the manufacturer regarding whether the CAC/HP product relies upon mandatory continuous circulation or not. (*Id.*) Further, Daikin suggested that whether a product uses continuous circulation or not could be validated by operation of the product when it is powered up, as well as validated by the safety agency (*i.e.,* NRTL) certification report. (*Id.*)

In response to Daikin's recommendation, DOE notes that it will consider certification requirements for CAC/HPs, including a requirement to certify whether the CAC/HP product relies upon mandatory constant circulation or not, in a separate rulemaking. However, DOE may validate whether a system utilizes constant circulation when powered up for the purposes of assessment or enforcement testing.

6. Dual-Fuel Heat Pumps

Heat pumps generally have reduced capacity and perform less efficiently at low ambient outdoor temperatures than they do at moderate ambient outdoor temperatures. Most heat pumps require some form of auxiliary heat when outdoor temperature is low to satisfy building load in excess of heat pump capacity. DOE is aware of HPs that combine the operation of a conventional electric HP with back-up heat provided by fuel, such as a gas fuel-fired furnace or boiler. 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.

The AHRI 210/240–202X Draft and AHRI 1600–202X Draft included a new definition for dual-fuel heat pump systems. Additionally, the two AHRI drafts introduced 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 according to the draft standards is optional, requires no additional testing, and is outlined in appendix L of both standards.

In the April 2024 NOPR, DOE tentatively determined that while the definition and optional test approach included in the draft industry standards may provide a representative test approach for dual-fuel heat pump systems, DOE was at that time continuing to evaluate whether to include such provisions in its CAC/HP test procedures. 89 FR 24206, 24229. Therefore, DOE proposed to not 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. *Id.*

AHRI 210/240–2024 and AHRI 1600–2024 finalized the definition and optional seasonal efficiency metric, DFUE, for dual-fuel heat pump without substantial change. Based on DOE's continued evaluation of the dual-fuel provisions in the two AHRI drafts, DOE has concluded that such provisions are not necessary in the CAC/HP test procedures. Therefore, DOE is not incorporating by reference the new definition of dual-fuel heat pump and

the optional seasonal efficiency metric, DFUE, outlined in the AHRI 210/240–2024 and AHRI 1600–2024. However, DOE recognizes that representations of dual-fuel heat pump performance may be useful to consumers. Therefore, while DOE is not proposing provisions for dual-fuel heat pumps, DOE would allow manufacturers to make optional representations of dual-fuel heat pump performance consistent with available AHRI industry test standards.

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—EER2, SEER2, HSPF2, EER, SCORE and SHORE for CAC/HP, and AFUE for consumer furnaces; regardless of whether a manufacturer chooses to rate their dual-fuel heat pumps with the DFUE metric. DOE also notes that the current representation requirements at 10 CFR 429.16 require representation of every individual heat pump combination distributed in commerce. As such, installing an outdoor HP unit and an indoor coil with an existing furnace (or other air mover) that is not being replaced would constitute distribution in commerce of a coil-only heat pump combination for which DOE requires a coil-only representation.

7. Rating Individual Components of Split Systems

(a) Background

DOE's test procedure in appendix M1 and its rating and certification requirements for central air conditioners and heat pumps in 10 CFR 429.16 have provisions that apply based on the configurations in which these products are distributed in commerce. This includes provisions for outdoor units of a split system that are not distributed in commerce with any indoor units, which DOE's regulations refer to as an outdoor unit with no match (''OUWNM'').

Specifically, 10 CFR 429.16(b)(2) requires that the ratings for basic models of split-system central air conditioners or heat pumps distributed in commerce as an OUWNM be based on the testing of a model of coil-only indoor unit meeting the requirements of section 2.2e of appendix M1. Section 2.2.e of appendix M1 requires that an OUWNM 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 OUWNMs 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.

In a final rule published on October 24, 2023 (''October 2023 EPA final rule''), pursuant to provisions of the American Innovation and Manufacturing Act (''AIM Act''), enacted on December 17, 2020 (42 U.S.C. 7675), EPA 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 ''specified components'' being installed were manufactured or imported prior to January 1, 2025 (''December 2023 EPA interim final rule''). 88 FR 88825.

Split-system CAC/HPs are included in the scope of residential and light commercial systems As such, new 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 provides an exemption, permitting the sales of specified components, to allow consumers to service and repair existing systems that are over the GWP limits defined in the October 2023 EPA Final Rule, provided the specified components are used only to service existing systems and are subject to labeling and reporting requirements. 88 FR 73098, 73124–73125. This provides an exemption for individual specified components of R–410A based split-system CAC/HPs to be sold as replacements, including condensing units and evaporator units, similar to the component exemption adopted by the EPA when R–22 was phased out. 74 FR 66450, 66459–66460.

(b) NOPR Proposal

In the April 2024 NOPR, DOE noted that while the current 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. 89 FR 24206, 24230. DOE noted that the current 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. *Id.* DOE clarified that per 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. *Id.* DOE further noted that, similar to EPA requirements for the R–22 ban, EPA is allowing such an outdoor unit to be installed as a replacement specified component for an existing system but not to be installed with indoor units for installation as a complete split CAC/HP system. *Id.*

DOE noted that appendix M1 currently does not explicitly define outdoor units with no match and that 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. *Id.* 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 proposed not to incorporate the definition by reference, and instead proposed a clarifying definition that is consistent with DOE's intention in the June 2016 Final Rule. *Id.*

DOE proposed the following definition for OUWNM in the April 2024 NOPR for appendix M1:

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,

(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 2 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 percent 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.

DOE noted that 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. *Id.*

DOE tentatively concluded that the proposed definition 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. *Id.* As proposed, the definition would apply to all types of outdoor units (*i.e.,* heat pump, air conditioner, single-speed, two-speed, variable-speed, etc.) and outdoor units with no match would continue to be tested with an indoor coil having a 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). *Id.* DOE clarified that the determination of represented values, alternative efficiency determination method (''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. *Id.* DOE noted that 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. *Id.* DOE noted that 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; however, the outdoor unit model could still be assigned the same individual model number. *Id.*

(c) Interaction With EPA Regulations

In response to its April 2024 NOPR, DOE received comments from stakeholders on a variety of issues related to compliance with DOE's regulations in the context of the October 2023 EPA Final Rule. These specific comments are addressed in the next section, but to ensure clarity this section first summarizes the key elements of compliance with DOE testing, rating, and certification requirements for these products during the period of implementation of the EPA rules.

As specified in the October 2023 EPA Final Rule, and modified in the December 2023 EPA interim final rule, installation of central air conditioner and heat pump systems manufactured or imported on or after January 1, 2025, that use a refrigerant with a GWP higher than 700 would be prohibited from being installed beginning on January 1, 2025. A system comprised of ''specified components'' manufactured or imported prior to January 1, 2025, can still be installed until January 1, 2026. The EPA's rule permits the continued manufacture, distribution, and installation of individual specified components that use higher GWP refrigerants on or after January 1, 2026, only as replacements for components in existing systems provided they are labeled for this use as specified in the EPA rule.

The DOE definition of the term ''central air conditioner or central air conditioning heat pump'' in 10 CFR 430.2 specifies that 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. Further, the DOE definition specifies that 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). In addition, DOE's requirements in 10 CFR 429.16(a) specify required representations based on how the model is distributed in commerce (*i.e.,* as part of a matched system, as an indoor unit only, or as an outdoor unit with no match).

DOE's rules for testing and rating covered products to establish compliance with energy conservation standards apply to basic models as distributed in commerce by the manufacturer (or importer). Although the deadlines for installation of specified components under EPA's rule apply to certain products based on their date of manufacture or import (*i.e.,* depending on whether they were manufactured prior to January 1, 2025), DOE's rules for how the manufacturer must test, rate, and certify their products apply based on the date of manufacture (or importation) and on how each basic model is distributed in commerce (*i.e.,* as part of a matched system or as an OUWNM), with the purpose being to ensure that each basic model complies with the energy conservation standard that applies to that basic model. A manufacturer or importer is not required to retest and/or recertify a basic model unless the manufacturer either makes a change to that basic model that would make it a new basic model under DOE's definition of that term in 10 CFR 430.2 or makes a change to the configuration in which it is being distributed in commerce such that a different tested combination requirement applies to it under 10 CFR 429.16. Stated within the context of the EPA's rule, a basic model of condensing unit that previously had been rated and certified to DOE in one or more combinations would not have to be re-tested and rated under the OUWNM provisions until such a time as the manufacturer ceases distribution of that basic model as part of a matched pair and begins distributing it as an OUWNM. At that point, the manufacturer must test, rate, and certify that condensing unit under the OUWNM as a new basic model, as under the basic model definition in 10 CFR 430.2 the model as an OUWNM cannot be the same basic model as it would have been in a combination.

For R–410A (or other refrigerant with GWP above 700) outdoor units manufactured (or imported) prior to January 1, 2025, which under the EPA's rule can still be installed as a system until January 1, 2026, the certifications of those models based on their tested combinations remain valid under DOE regulations as long as manufacturers continue to distribute them in commerce as a system. However, if at some point the manufacturer chooses to distribute in commerce the unit alone and not as a combination with any indoor units (either before January 1, 2026 or after that date as a service-only replacement component to comply with EPA's rule), the outdoor unit would have to be tested, rated, and certified in accordance with the OUWNM provisions. This also applies for R–410A (or other refrigerant with GWP above 700) outdoor units manufactured or imported on or after January 1, 2025, as DOE expects that manufacturers would cease distribution of the outdoor units

as part of a combination, as these systems could no longer be installed anywhere in the U.S. This certification as a new basic model must be made prior to the date at which the manufacturer begins distributing those outdoor units as an OUWMN and would be indicated to DOE in its certification reports via a discontinued model filing for the model as distributed in a combination and certification as a new basic model of OUWNM.

For an indoor unit intended only for replacement in an existing system and which is no longer distributed in commerce for installation as a combination, as would be the case for an existing system that uses a refrigerant banned by EPA, the requirement in 10 CFR 430.2 and table 1 of 10 CFR 429.16(a) for the indoor unit to be rated as part of a system would still apply even though the indoor unit is no longer being distributed in commerce as part of a combination. This rating requirement would apply regardless of whether the manufacturer of the indoor unit is an ICM. If the indoor unit uses a refrigerant allowed by EPA only for component replacement (*e.g.,* R–410A), the rating for such a unit would be based on a combination using that refrigerant, and per EPA regulations could not be distributed in commerce as a combination. However, this does not imply that the indoor unit cannot be rated, nor that the entire system would have to be replaced. DOE notes further that any such rating for the indoor unit must be compliant with current standards, and that any indoor units distributed in commerce for use in a system that uses a refrigerant subject to the EPA ban would need to have been certified to DOE as compliant with the applicable standards as part of a combination before January 1, 2025 and must have been tested and rated in every combination with an outdoor unit with which it has been previously distributed in commerce.

(d) Comments Received

In their response to the NOPR, the Joint Advocates and Lennox fully supported the proposed provisions for OUWNMs. The Joint Advocates agreed that DOE's clarifying definition for OUWNM will help ensure representative ratings and that the proposed definition is consistent with DOE's intent in the June 2016 Final Rule. (Joint Advocates, No. 30 at p. 3) Lennox strongly supported the DOE proposal that 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. (Lennox, No. 24 at p. 2).

Several commenters requested more clarity or expressed concerns on DOE's OUWNM provisions. These are discussed in the following subsections.

(1) OUWNM Definition

AHRI commented that while the definition of "OUWNM" in AHRI 210/240-2024 and AHRI 1600-2024 is specifically focused on R-22 outdoor units, in line with the current regulations in the DOE test procedure, AHRI is taking steps to update the standards to ensure that OUWNM provisions are applicable to any outdoor units that are distributed in commerce without an indoor matching pair, regardless of the refrigerant the outdoor unit employs. (AHRI, No. 25 at p. 4) AHRI noted that it intends to expedite revisions to AHRI 210/240-2024 and AHRI 1600-2024 to reflect OUWNM definitions adopted in the final rule. (*Id.*) AHRI suggested modification to part of the proposed definition of OUWNMs (proposed additions *italics* and deletions in ~~strikeout~~) as follows:

An Outdoor Unit that is not distributed in commerce *by the manufacturer* 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 *a new* Indoor Unit as a system, according to EPA regulations in 40 CFR chapter I, subchapter C,

[provisions (b) and (c) unchanged]

Rheem requested that DOE consider simplifying the proposed definition for OUWNMs because some of the bullet points may overlap or conflict with each other. (Rheem, No. 34 at p. 3) Rheem noted that in SNAP Final Rule 237, EPA has approved R–32, R–452B, R–454A, R–454B, R–454C, and R–457A for use in residential and light commercial air-conditioning and heat pump end use, which also includes CAC/HPs. (*Id.*) Rheem commented that among these substitutes, R–454C and R–457A have a 95 °F midpoint saturation absolute pressure within 18 percent of the 95 °F saturation absolute pressure for R–22, thus meeting the provisions in 4.1(b) and 3.1(b) of the proposed OUWNM definition at appendix M1 and appendix M2, respectively. (*Id.*) Rheem suggested that DOE simplify the definition of OUWNM to avoid confusion. (*Id.*)

DOE appreciates that AHRI is taking steps to update AHRI 210/240–2024 and AHRI 1600–2024 standards to broaden the OUWNM provisions beyond R–22 outdoor units and make them applicable to any outdoor units that are distributed in commerce without an indoor matching pair, regardless of the refrigerant the outdoor unit employs. Such an implementation would be consistent with DOE's proposed definition of OUWNMs in the April

2024 NOPR. DOE disagrees with the addition of ''by the manufacturer'' in the OUWNM definition to qualify distribution in commerce, since under EPCA the term ''distribution in commerce'' also applies to subsequent distribution after the initial offering by the manufacturer. The proposed addition would undercut the general applicability of that term across the distribution chain as established in EPCA. As explained in DOE's March 7, 2011, final rule that established the certification provisions in Part 429, application of the term ''distribution in commerce'' would depend on a particular manufacturer's production practices, business decisions, and the facts and circumstances of a particular case. 76 FR 12422, 12426. . However, DOE agrees with the inclusion of the term ''new'' to clarify that the EPA ban specifically pertains to new system installations, and for further clarification is including the term ''new'' to describe both the indoor unit with which the outdoor unit is paired and the newly created system. In addition, notwithstanding the broad applicability of the term ''distribute in commerce,'' DOE notes that under 10 CFR 429.102(a)(6) it is a prohibited act for a manufacturer or private labeler to distribute in commerce any new covered product or covered equipment that is not in compliance with an applicable energy conservation standard prescribed under the Act, and therefore the obligation to certify that basic models are in compliance with the standards lies with the manufacturer and importer. This is also the basis for the requirement in 10 CFR 429.12(a) that each manufacturer, before distributing in commerce any basic model of a covered product or covered equipment subject to an applicable energy conservation standard, certify that the model meets the applicable energy conservation standard.

DOE agrees with Rheem that certain SNAP-approved refrigerants, for example R–454C and R–457A, have pressure-temperature relationship characteristics similar to R–22 and would meet provision (b) of the proposed OUWNM definition. DOE notes that both these refrigerants have GWPs equal to or less than 150, and thus could potentially be under consideration for future reductions in GWP as compared with refrigerants R–454B and R–32, the primary near-term candidates for transition from R–410A. To ensure that these SNAP-approved refrigerants would not be subject to provision (b) of the proposed OUWNM definition, DOE is qualifying provision (b) with a GWP limit—specifically, only refrigerants with GWP greater than 150 (per EPA's measure) would be subject to provision (b).

In summary, DOE is making minor modifications to the OUWNM definition as follows:

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 a new 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 and a global warming potential greater than 150 per EPA regulations in 40 CFR 84.64; or

(c) Is shipped without a specified refrigerant from the point of manufacture or is shipped such that more than 2 pounds of refrigerant are required to meet the charge per section 5.1.8 of AHRI 210/240–2024.[36] This shall not apply if either (a) the factory charge is equal to or greater than 70 percent 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.

(2) Clarity on Interaction With EPA Rule

AHRI and Carrier requested further clarity on how DOE's OUWNM provisions will interface with the October 2023 EPA final rule, particularly in terms of timing and scope. (AHRI, No. 25 at pp. 2–4; Carrier, No. 29 at p. 3)

AHRI appreciated DOE's proposal to expand the OUWNM definition to include HFC refrigerants having a GWP greater than 700, in line with EPA's ban, but noted that the interaction between the EPA and DOE regulations are complex and implementation questions remain. (AHRI, No. 25 at p. 2) AHRI cautioned that care must be taken to ensure industry and downstream distribution partners understand and can remain compliant with applicable regulations and that consumers who recently installed products with R–410A refrigerant have meaningful access to service parts for the useful life of their equipment. (*Id.*) AHRI noted that while no date has been included with the DOE-proposed OUWNM definition, the NOPR preamble presents the proposed date of 2026. (AHRI, No. 25 at p. 3) AHRI sought clarification that OUWNM ratings would only be required for split-system outdoor units using HFC refrigerants having a GWP greater than 700 manufactured after January 1, 2025. (*Id.*) AHRI attached a spreadsheet (Exhibit 1) that contained requests for clarification from DOE on questions regarding the prohibitions for manufacture, distribution, and installation of various product types. (AHRI, No. 25 at pp. 5–6). Specifically, AHRI requested clarification on whether DOE's proposal applies to split-system CAC/HP products imported into the United States, but which are not for sale in the United States. (*Id.*)

Carrier appreciated DOE's intent to further clarify the OUWNM requirements and noted that it is clear that the OUWNM category is the equivalent of EPA's service-only condenser allowance in the market. (Carrier, No. 29 at p. 3) Carrier commented that it supports DOE stating the application of OUWNM requirements to a service-only R–410A condensing unit, but requested that DOE provide additional clarity in the final rule on certain aspects, including effective date, which unit types OUWNM applies to, and the indoor airflow requirements. (*Id.*) In particular, Carrier requested that DOE make the following clarifications to better help the regulated community in complying with applicable efficiency and refrigerant regulations: (1) R–410A condensing units manufactured or imported on or after January 1, 2025 would need to be tested and rated as an OUWNM because EPA prohibits the installation of those outdoor units with a new indoor unit; (2) any R–410A outdoor and indoor units manufactured before January 1, 2025 could be sold and installed utilizing the existing DOE-certified system rating, because EPA is allowing installation; (3) since EPA prohibits the sale and installation of any R–410A outdoor and indoor units in 2026 regardless of production date, any remaining pre-2025 inventory held by a manufacturer would be required to be recertified using the OUWNM procedure when distributed in commerce on or after January 1, 2026; and (4) any pre-2025 R–410A air conditioners in the Southeast or Southwest regions could not be installed without being recertified as an OUWNM. (Carrier, No. 29 at p. 3)

In response to AHRI, DOE clarifies that OUWNM ratings for split-system outdoor units employing refrigerants with GWP greater than 700 would be required for units distributed in commerce as service-only placement

[36] For Appendix M2, the definition references section 5.1.8 of AHRI 1600–2024.

components (*i.e.,* not as a combination) from the point of manufacture and thus subject to DOE's testing and rating requirements for outdoor units with no match in Appendix M1 and 10 CFR 429.16. As discussed in the previous section of this notice, DOE expects that manufacturers would need to make this transition for units manufactured after January 1, 2025, which it intends to make available as service-only replacement components for existing systems. Regarding units that are imported into the United States but not distributed and sold for installation within the United States, DOE notes that its requirements specified in 10 CFR parts 429, 430, and 431 shall not apply to any covered product or covered equipment if: (a) such covered product or covered equipment is manufactured, sold, or held for sale for export from the United States or is imported for export; (b) such covered product or covered equipment or any container in which it is enclosed, when distributed in commerce, bears a stamp or label stating ''NOT FOR SALE FOR USE IN THE UNITED STATES''; and (c) such product is, in fact, not distributed in commerce for use in the United States. 10 CFR 429.6.

DOE notes that the additional detail provided in the preceding section of this notice, and in the preceding paragraphs, is largely consistent with Carrier's suggestions. However, DOE wishes to correct two of Carrier's clarifications: (1) the recertification of remaining pre-2025 inventory would not be required provided those basic models were correctly certified based on how they were distributed at the time of their manufacture; and (2) the applicability of these provisions for units to be installed in the Southeast or Southwest do not differ from products subject to nationwide standards. The only difference for installation in the Southeast or Southwest is that the regional energy conservation standards would apply for such installations, as would otherwise be the case per 10 CFR 430.32(c)(6), and the efficiency rating as certified by the manufacturer must indicate those basic models comply with the applicable regional standards and may be installed in the Southeast and/or Southwest regions.

(3) Recertification of Units Already Distributed in Commerce

Several commenters expressed concern with the recertification as OUWNMs of units already distributed in commerce, when installed after January 1, 2026.

AHRI sought clarification on the intended meaning of the phrase ''distributed in commerce.'' (AHRI, No. 25 at p. 3) AHRI noted that the current DOE regulation places no restrictions on distribution of products if the product was initially certified and regional standards are not an issue for the product and location. (AHRI, No. 25 at p. 6) AHRI noted that DOE's NOPR proposal requires existing outdoor models currently distributed in commerce as part of a split-system basic model that transition to a replacement outdoor unit only to be tested, rated, and recertified under the provisions in 10 CFR 429.16 for an outdoor unit with no match. (*Id.*) AHRI noted that per EPCA, ''distribution in commerce'' means ''to sell in commerce, to import, to introduce or deliver for introduction into commerce, or to hold for sale or distribution after introduction into commerce,'' and that ''distribution in commerce'' applies to both the initial offering for sale by the manufacturer and the subsequent distribution by downstream partners (*i.e.,* sale by the distributor to the contractor, or the contractor to the homeowner). (*Id.*) AHRI cautioned that without linking the requirements to a manufacture/import date, DOE's proposal complicates the distribution of outdoor units manufactured pre-2025 that are no longer in possession of the manufacturer or private labeler. (*Id.*) AHRI questioned how DOE will enforce the proposal on products subject to national energy efficiency standards. (*Id.*)

AHRI contended that for products subject to national standards, DOE is constrained by the application of the base national standard, which ''applies to all products manufactured or imported into the United States on and after the effective date of the standard.'' [37] (AHRI, No. 25 at p. 6) Therefore, AHRI asserted that space-constrained products; small-duct high-velocity, air conditioners in the North; and heat pumps manufactured or imported prior to January 1, 2025 that were certified as compliant with the base national standard can still be installed in the United States until the inventory is depleted. (*Id.*) AHRI questioned how DOE could require manufacturers, distributors, or contractors to retroactively apply testing, rating, or certification requirements on outdoor units subject to national standards that were distributed in commerce and are no longer in the manufacturer's possession. (AHRI, No. 25 at pp. 6–7) AHRI requested for DOE to link the OUWNM definition to a manufacture/import date, as DOE's proposal complicates the distribution of outdoor units manufactured prior to January 1, 2025 that are no longer in possession of the manufacturer (or private labeler). (AHRI, No. 25 at p. 7) Similarly, for products subject to regional standards, AHRI questioned how DOE could require manufacturers, distributors, or contractors to retroactively apply testing, rating, or certification for outdoor units manufactured/imported in 2024 and no longer in possession of the manufacturer. (*Id.*) AHRI requested clarification on whether DOE intended that air conditioners slated for the Southeast and Southwest regions, manufactured/imported in 2024, and still in possession of the manufacturer be recertified as OUWNMs on January 1, 2025. (*Id.*)

AHRI noted that while the NOPR preamble states that ''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,'' DOE has not described in the proposed regulatory text how the testing, rating, and recertification for outdoor units distributed in commerce by outdoor unit manufacturers (''OUMs'') for a former certified combination that transitions to OUWNMs for replacement will be completed. (AHRI, No. 25 at p. 6) AHRI expressed concern that this may create logistical complications, given that ''distributed in commerce'' applies to both the initial sale and the subsequent sale of products that have already entered commerce and are no longer in the possession of the manufacturer to be recertified. (*Id.*) AHRI contended that certification of a condensing unit as an OUWNM should apply to products manufactured after January 1, 2025. (*Id.*)

HARDI strongly opposed any restriction on the ability of its members to sell products already in inventory, including install date regulations, such as EPA's transitions program and the statutorily required install date in DOE's regional standards for split-system central air conditioners. (HARDI, No. 26 at pp. 1–2) HARDI commented that it believed install date requirements hinder the ability of the heating, ventilation, air-conditioning, and refrigeration industry to move to more energy-efficient or environmentally friendly products and that install date regulations that cause dead inventory are ineffective because they create waste, increase costs, and constitute a

[37] 42 U.S.C. 6295(o)(6)(E).

regulatory taking.[38] (*Id.*) HARDI commented that it was its understanding that the phrase ''currently distributed in commerce'' does not intend to include CAC/HP equipment already in distributors' warehouses, but it asserted that, just like with the confusing compliance regime caused by the install date associated with regional standards for split-system central air conditioners, if this phrase is used in the final regulation, local compliance officials will prevent repairs to existing systems if the outdoor unit does not have proof of meeting the minimum efficiency standard. (HARDI, No. 26 at p. 2) HARDI suggested that the best course of action is to apply the OUWNM testing and certification requirements at the same date of manufacture timeline as the EPA requirement for outdoor condensing units to be marked ''For servicing existing equipment only.'' (*Id.*) HARDI noted that for split-system CAC/HPs, EPA requires anything manufactured after January 1, 2025 to be marked ''For servicing existing equipment only.'' (*Id.*) HARDI further noted that while new split-system CAC/HPs can be installed until January 1, 2026 using R–410A or other high-GWP refrigerants, EPA requires those systems to be manufactured before January 1, 2025, and outdoor units manufactured after January 1, 2025 can only be used as components, thereby meeting the proposed definition of OUWNMs. (*Id.*) HARDI recommended that DOE limit the need to test, rate, and recertify equipment to only outdoor units manufactured after January 1, 2025, as this will ensure that equipment intended to be installed as an OUWNM does meet the minimum efficiency requirements while not affecting equipment originally sold for installation as a matched system. (*Id.*)

JCI expressed concerns with DOE's proposal to require recertification of units ''currently distributed in commerce'' to meet the OUWNM requirements, contending that requiring recertification of a component as part of a system that was previously certified as compliant and has already entered commerce, *i.e.,* is no longer in the possession of the original manufacturer, is overly burdensome for manufacturers, distributors, and contractors, and will be problematic for DOE to enforce without tying enforcement to the manufacture/import date. (JCI, No. 35 at p. 2) JCI recommended that for outdoor units that have entered commerce, the ''date of manufacture'' be used as the enforcement mechanism. (*Id.*) JCI commented that it was its understanding that outdoor units manufactured on or after January 1, 2025 would be required to meet DOE's OUWNM criteria if they were still in the possession of the original manufacturer. (*Id.*) JCI stated that clarifying that the OUWNM requirements would take effect on January 1, 2025, versus the NOPR date of January 1, 2026, reduces the amount of inventory in the channel that would require recertification. (*Id.*)

Rheem also expressed concern about language for OUWNMs applicable to ''existing outdoor models currently distributed in commerce,'' where these products would need to be recertified and given a new basic model number in the event that they are only eligible for component replacement per EPA's Technology Transitions rule. (Rheem, No. 34 at p. 3) Rheem asserted that the notion of obtaining proof of new rating and a different model number is unreasonable to require once the equipment has left manufacturer warehouses, as the application of new labels and rating certifications is impractical to carry out at the distributor and installer levels. (*Id.*) Rheem commented that EPA appears to recognize this impracticality and does not require relabeling of equipment made prior to January 1, 2025 to indicate ''for service only.'' (*Id.*) Rheem contended that a change in the test procedure should not render obsolete a product currently in commerce that was compliant at the time of manufacture. (*Id.*)

As indicated by AHRI, DOE notes that per EPCA, the terms ''to distribute in commerce'' and ''distribution in commerce'' mean to ''sell in commerce, to import, to introduce or deliver for introduction into commerce, or to hold for sale or distribution after introduction into commerce.'' (42 U.S.C. 6291(16)) Under the statutory definition, this term can apply to the initial offering of sale by a manufacturer or by subsequent distribution by downstream partners. As was discussed in the previous section, the December 2023 EPA Interim Final Rule allows for a 1-year sell-through period (until January 1, 2026) for any CAC/HP system employing a refrigerant with a GWP of 700 or greater, provided the specified component is manufactured or imported prior to January 1, 2025 (*see* 40 CFR 84.54(c)(1)). Since EPA prohibits the installation of any specified CAC/HP components to create a new system employing a refrigerant with a GWP of 700 or greater on or after January 1, 2026, irrespective of the manufacturing date, any remaining pre-2025 inventory (*i.e.,* imported or manufactured before January 1, 2025) held by any channel of distribution (manufacturer or distributor) could not be installed as a system after January 1, 2026.

DOE's rating and certification requirements in 10 CFR 429.16 for central air conditioners and heat pumps apply based on how a manufacturer distributes the models in commerce. If the manufacturer ceases distribution in commerce of a model of outdoor unit that was previously part of a combination and begins distributing it only as an OUWNM to allow for use as a service-only replacement under the EPA's rules for components of an R–410A system, that model of outdoor unit would need to be recertified under the OUWNM requirements regardless of when that transition occurs, since the manufacturer (or private labeler) has an obligation to ensure that any basic model it distributes is compliant with the applicable energy conservation standard for the configuration (or configurations) in which the manufacturer distributes it. However, the requirement to recertify those basic models does not apply retroactively to units of a basic model that were already distributed in commerce as part of a combination and had been correctly certified according to DOE's regulations.

Regarding AHRI's concern about enforcement of national standards, DOE notes that no changes were proposed to national standards in the April 2024 NOPR, and none are being finalized in this rulemaking. The purpose of the clarification provided in this rulemaking is to ensure that manufacturers have a clear understanding of how to comply with DOE's certification requirements for products that will be subject to EPA regulations. DOE's certification provisions in 10 CFR 429.12(a) specify that each manufacturer, before distributing in commerce any basic model of a covered product or covered equipment subject to an applicable energy conservation standard set forth in parts 430 or 431, and annually thereafter . . . shall submit a certification report to DOE certifying that each basic model meets the applicable energy conservation standard(s). To the extent that outdoor units that were previously certified as compliant as part of a matched system begin being distributed in commerce as outdoor units with no match, they are being distributed as a new basic model, and therefore, must certify compliance with the applicable energy conservation

[38] HARDI notes that a regulatory taking is a ''taking of property under the Fifth Amendment by way of regulation that seriously restricts a property owner's rights,'' *Blacks Law Dictionary,* 11th Edition. (HARDI, No. 26 at p. 1).

standards. The application of the base national standard, as referenced by AHRI, still applies to the outdoor unit based on its manufacture date, but compliance with that standard must be determined for the basic model distributed in commerce (*i.e.,* the OUWNM).

DOE notes that the EPA regulations include a 1-year sell-through period to reduce inventory of units that may be in danger of not complying with the EPA rule. DOE's rationale also applies to AHRI's concern on regional standards. However, DOE notes that there is confusion on the applicability of the EPA dates on the regional level. DOE clarifies, consistent with the national application, that air conditioners certified as able to be installed in the Southeast and Southwest regions manufactured or imported before January 1, 2025, and that have already been distributed in commerce, would not need to be certified as OUWNMs on January 1, 2025, provided the manufacturer had already certified compliance with the applicable energy conservation standards. For units intended for installation in the Southeast or Southwest regions, this would include a certification that they comply with those applicable standards. As previously explained in this notice, the only distinction from CAC/HP products that are not subject to regional efficiency standards is that split-system AC outdoor units certified as OUWNM would have to meet the applicable standards for the Southeast or Southwest regions to be installed in those regions.

DOE notes there may be confusion regarding the applicability of the compliance dates in the EPA rule and how these dates affect DOE regional standards requirements. To be clear, the EPA rule has no effect on DOE requirements. For certain split-system central air conditioning systems or certain OUWNMs to be installed in the Southeast or Southwest region consistent with DOE regional standards requirements, the system/OUWNM must be certified to DOE as compliant with the applicable regional standard(s), and the certification must indicate that the model/combination can be installed in the Southeast and/or Southwest region. While the EPA rule may change the approach a manufacture may take with respect to testing and certifying a particular model, it does not change DOE requirements.

In response to AHRI's concern that DOE has not described in the proposed regulatory text how the testing, rating, and recertification for OUWNMs will be completed, DOE notes that the testing requirements are laid out in section 4.2 of revised appendix M1 and section 3.2 of new appendix M2. Additionally, as noted in the April 2024 NOPR, and explained in the preceding section of this notice, existing outdoor models currently distributed in commerce as part of a split-system basic model that the manufacturer transitions to a replacement outdoor unit only would need to be tested, rated, and certified under the provisions in 10 CFR 429.16 for an outdoor unit with no match. 89 FR 24206, 24231. As described previously in this section, distribution of such a model as an OUWNM represents distribution in commerce of a new basic model, and accordingly, the basic model must be certified as compliant with the applicable energy conservation standards. DOE may consider additional certification requirements under a separate rulemaking regarding appliance and equipment certification.

In response to HARDI, DOE clarifies that the reporting obligations apply to manufacturers, and importers, and thus basic models previously distributed in commerce by the manufacturer that were certified by the manufacturer in accordance with 10 CFR 429.12 do not need to be recertified. Regarding HARDI's criticism of regulation based on install date requirements, DOE clarifies that, whereas the EPA rule is based on the date of installation, the application of the OUWNM provisions are based on the configuration in which the manufacturer (or importer) distributed the basic model from the point of manufacture (or import). It does not depend upon distributor or retail sales and offerings. DOE notes that the EPA regulations include a 1-year sell-through period for pre-2025 inventory to provide time to reduce inventory. The OUWNM provisions in this rulemaking simply align with the EPA action undertaken in the October 2023 EPA rule. In response to HARDI's recommendation to limit the need to test, rate, and recertify equipment to only outdoor units manufactured after January 1, 2025, DOE agrees that most inventory manufactured prior to January 1, 2025, will likely be distributed in commerce with indoor units and be installed prior to January 1, 2026; however, to the extent that any outdoor units manufactured prior to January 1, 2025, continue to be distributed in commerce by the manufacturer after January 1, 2026, as OUWNM, the manufacturer must test consistent with the requirements applicable to OUWNMs and certify the compliance of such models with the applicable energy conservation standard.

In response to JCI, DOE again stresses that the timing for implementation of the OUWNM provisions is tied to the EPA rule. Specifically, an outdoor unit no longer has a match when EPA requirements no longer allow installation with an indoor unit to create a new system, and thus must be certified to DOE as an OUWNM as it continues to be distributed in commerce. As discussed in III.E.7.c(2), DOE clarifies that any outdoor CAC/HP units manufactured or imported on or after January 1, 2025 and employing refrigerants with GWP greater than 700 (for example, R–410A), would need to be tested and rated as an OUWNM, consistent with the EPA requirement that such models be used ''for servicing existing equipment only.'' For units manufactured or imported before January 1, 2025 the existing DOE-certified system rating can be used, provided the manufacturer does not continue distribution of the outdoor units alone, because the EPA regulations permit installations of such systems until January 1, 2026. However, if the unit is distributed in commerce alone and not as a combination with any indoor units, as likely would be the case for products intended for installation as an individual replacement component of an existing system, the outdoor unit would have to be certified in accordance with the OUWNM provisions prior to the date at which the manufacturer begins distributing those outdoor units as an OUWMN, as indicated to DOE in its certification reports via a discontinued model filing for the model as distributed in a combination and certification as an OUWNM.

In response to Rheem's claim that EPA does not require relabeling of equipment made prior to January 1, 2025 to indicate ''for service only,'' DOE notes that the EPA labeling requirement at 40 CFR 84.58(b) states, ''Effective upon the date listed for each subsector in § 84.54(c) . . . any specified component . . . that uses or is intended to use any regulated substance, or blend containing any regulated substance . . . must have a permanent label compliant with paragraph (c) [39] of this section containing the information in paragraph (a)(1) of this section. For specified components that are intended for use

[39] The reference is to paragraph (c) but should be to paragraph (d), which specifies label design (*e.g.,* English language, durable and printed/affixed to the product exterior surface, readily visible and legible, etc.). Paragraph (c) addresses products in the foam or aerosol sector and is not relevant for the refrigeration, air-conditioning, and heat pump sector addressed in paragraph (b).

with a regulated substance or blends containing a regulated substance that exceed the applicable GWP limit or HFC restriction, the label must state ''For servicing existing equipment only'' in addition to the other required labeling elements.'' (*See* 40 CFR 84.58(b)) 40 CFR 84.58(c) requires the label to list, at a minimum, the refrigerant and the date of manufacture. DOE is aware that there are two dates listed in the relevant paragraph for split-system CAC/HPs under section § 84.54(c)—January 1, 2025 and January 1, 2026. As discussed above and in the preceding section of this notice the December 2023 EPA Interim Final Rule pushed back the restriction on R–410A and similar refrigerants such that components manufactured prior to January 1, 2025 could be installed as part of systems prior to January 1, 2026, and thereafter would be installable only for servicing existing equipment. Thus, unless EPA intended for the ''for servicing existing equipment only'' words to be on specified components starting January 1, 2025, when they would still be allowed to be used for system installations, EPA regulations effectively state that the required label would have to be applied or changed while the component is in distribution, *i.e.,* after leaving the manufacturer but before installation. However, DOE notes that these labeling provisions are separate from its own regulatory requirements and that manufacturers seeking more specific guidance on the implementation of these provisions should consult EPA.

Regarding Rheem's contention that a change in the test procedure should not render a currently compliant product obsolete, DOE notes that it is the EPA action, and not a change to the DOE test procedure, that would prevent the installation of a previously certified CAC/HP system. In accordance with this EPA action, DOE's OUWNM provisions in the test procedure provide a means for manufacturers to assign an energy efficiency rating to split-system outdoor units after the EPA has banned them for full-system installations. As discussed earlier in this section and in the preceding section, to the extent that the manufacturer of the outdoor unit of a previously certified CAC/HP system begins distributing it in commerce as an OUWNM, it would become a new basic model and the manufacturer would need to certify that it complies with the applicable energy conservation standard.

In a comment related to concerns regarding recertification as OUWNM of outdoor units already distributed in commerce, GE Appliances indicated that products currently in production would need redesign to comply with cut-out/cut-in temperature and CVP enforcement testing. (GE Appliances, No. 37 at p. 6) They commented that since import and production of legacy R–410A equipment will cease after January 1, 2025, there will be no need to redesign existing inventory, in order to comply with the cut-out/cut-in temperature and CVP enforcement test. *Id.* They pointed out that most of DOE's energy efficiency enforcements are based on date of import or manufacture, so exclusion of R–410A legacy equipment from CVP and cut-out/cut-in enforcement testing would be consistent with this practice, and that failing to exclude these products from such enforcement would lead to stranded inventory, resulting in the loss of embodied carbon in the inventory, with little/no energy efficiency saving. *Id.*

In response to the comment by GE Appliances, certifications required to be made by a manufacturer for the compressor and indoor blower speed of any variable capacity system at specific test conditions must represent normal operation. The CVP provisions established in this final rule describe how DOE would verify that certified values are appropriate for the purposes of DOE enforcement testing. Hence, DOE would expect existing properly-certified variable speed CAC/HPs and CHPs to pass the CVP enforcement with minimal or no adjustment to existing performance representations. Further, DOE certainly would not expect changes sufficient to call into question the compliance of such models with DOE efficiency standards. Similarly, although cut-out and cut-in temperatures are not currently required to be certified, DOE would expect manufacturers to have certified HSPF2 values that are consistent with the actual cut-out/cut-in characteristics of certified models. Manufacturers are not required themselves to conduct CVP testing. To the extent that manufacturers are correctly certifying performance of existing models, there would be no need to recertify or redesign such models in response to DOE implementing CVP testing for enforcement purposes. Therefore, DOE disagrees with the suggestion of GE Appliances, that there should be specific exclusions for legacy R–410A CAC/HPs from the CVP and cut-out/cut-in temperature enforcement provisions.

(4) Applicability to Multi-Head Mini-Splits, Multi-Splits, and Multi-Circuit Systems

AHRI and Carrier requested clarity on whether the OUWNM provisions are applicable to multi-head mini-split, multi-split, or multi-circuit systems. (AHRI, No. 25 at pp. 4–5; Carrier, No. 29 at pp. 3–4).

Carrier requested that DOE confirm that the OUWNM certification requirement is applicable to all split-system condensing units within the scope of appendix M1, which includes single-split, multi-head mini-split, multi-split (including VRF), and multi-circuit air conditioner and heat pump systems. (Carrier, No. 29 at pp. 3–4) Specifically, Carrier commented that it believes multi-head mini-split and multi-split systems should also require the OUWNM certification. (*Id.*) Carrier noted that while these systems are generally intended to be installed with multiple indoor units, they can be installed with a single indoor unit, which could be ducted or ductless, and that multiple manufacturers have combinations that utilize a mini-split (traditionally known as a ''ductless outdoor unit'') with a conventional ''ducted'' indoor unit and coil combination. (*Id.*) Carrier further noted that multi-split and mini-VRF outdoor units are able to be rated, certified, and used in combination with a single indoor unit as well as the typical multiple indoor units. (*Id.*) Carrier expressed concern that if OUWNM provisions are not required for these systems that can be installed with a single indoor unit, they could be used to replace the condenser on a system with an indoor unit that was never a certified combination, yielding poor system efficiencies. (*Id.*) Carrier commented that it was its understanding that EPA's reasoning to allow a service-only condenser was to address the customer concern of replacing their entire system upon a part failure in the condenser. (*Id.*) Carrier stated that in its experience, this does not happen regularly in the market, and if there is a premature part failure in the condenser, the part (*i.e.,* compressor, expansion valve, motor, control board, or coil) is replaced or repaired, especially in the case of complex outdoor units such as multi-split condensers. (*Id.*) Carrier noted that in the situation the condenser fails at end of life, it is common practice to replace the entire system. (*Id.*) For these reasons, Carrier requested that DOE clarify that all split-system condensing units within the scope of appendix M1 that are manufactured beginning January 1, 2025 with R–410A or any banned refrigerant must be certified as an OUWNM. (*Id.*).

AHRI noted that appendix M1 defines the tested combination of a multi-head mini-split, multi-split, or multi-circuit system to consist of one outdoor unit

with one or more compressors matched with between two and five indoor units. (AHRI, No. 25 at p. 4) AHRI further noted that appendix M1 requires that these indoor units must collectively have a nominal cooling capacity greater than or equal to 95 percent and less than or equal to 105 percent of the nominal cooling capacity of the outdoor unit. (*Id.*) AHRI requested that DOE confirm (1) if multi-head systems would test as OUWNM with one or two indoor units per appendix M1, section 2.2(e); and (2) if the preference is for testing multi-head systems with two (or more) indoor units, whether the coil-only indoor unit coil shall be split evenly between the two, or in another configuration. (AHRI, No. 25 at pp. 4–5).

DOE agrees with the reasons presented by Carrier and clarifies that the OUWNM provisions are applicable to all split-system CAC/HPs within the scope of appendix M1—including single-split, multi-head mini-split, multi-split (including VRF), and multi-circuit air conditioner and heat pump systems. As noted by AHRI, per appendix M1, the tested combination of a multi-head mini-split, multi-split, or multi-circuit system requires between two and five indoor units. However, the indoor unit requirements (which are based on the highest sales volume family) are not explicitly applicable for OUWNM testing. As indicated by Carrier, multi-head systems can be installed and are able to be rated with either a single indoor unit or multiple indoor units. To provide maximum flexibility to manufacturers and to limit test burden, DOE clarifies that, for multi-head systems being certified under the outdoor unit with no match provisions, (1) multi-head systems capable of being paired with a single indoor coil shall be tested with a single indoor coil; and (2) multi-head systems incapable of being paired with a single indoor coil shall be tested with the least amount (between two to five) of identical indoor coils. If testing with two or more indoor coils, all coils shall have the same dimensions. The current testing instructions in section 2.2(e) of appendix M1 [40] are written for a single indoor coil, but the same concept of the NGIFS can be extended to two or more identical indoor coils. Specifically, when evaluating NGIFS with two or more indoor coils, the total summation of the fin surface area would include all coils. DOE may consider certification requirements to include whether one or more indoor coils were used to evaluate an OUWNM rating in a separate rulemaking.

(5) Control Type and Communicating System

Carrier also requested that DOE clarify that OUWNM certification is required for all condensing units, regardless of the control type being used to generate the system rating. (Carrier, No. 29 at p. 4) Carrier noted that many of the communicating variable-speed condensers on the market today also have the capability to operate with a conventional 24–V non-communicating thermostat and that it would be extremely difficult to exclude these units from the OUWNM certification and ensure they were actually being matched with a certified communicating indoor unit that was previously installed. (*Id.*)

Conversely, GE Appliances commented that multi-head ductless split systems and VRF systems under 65k BTU, which are almost always variable-speed communicating systems, are unable to complete the existing test procedure for an OUWNM listing, as existing software does not support or allow a coil-only match without connection to a matched indoor unit. (GE Appliances, No. 37 at p. 4) GE asserted that the inability to provide replacement outdoor units to service existing communicating systems will lead to significant harm for consumers, the environment, and DOE's goals for heat pumps and variable-speed systems. (*Id.*) GE Appliances requested that DOE allow outdoor-unit-only listings for variable-speed communicating systems capable of supporting multiple indoor coils based on the lowest-performing system performance for the outdoor coil for any previously listed system or currently produced, compatible communicating coil. (*Id.*) GE Appliances asserted that because outdoor units for communicating systems can generally only work with matched indoor units using the same communications protocol, there is little risk of improper combinations to create systems that perform worse than efficiency levels required by DOE. (*Id.*) GE Appliances further commented that listing OUWNM units for these systems in this manner ensures accurate consumer information about expected product performance and also ensures service components' availability where they would otherwise be restricted. (*Id.*)

Mitsubishi also asserted that while it understands the broad industry support for DOE to extend the definition of OUWNM to R–410A outdoor units, the proposed language does not take into account the emergence and expansion of communicating variable-speed equipment. (Mitsubishi, No. 28 at p. 2) Mitsubishi contended that like every other inverter-driven variable-capacity ductless OEM, Mitsubishi systems and components are unable to test or operate with any coil in a lab or in the field that is not equipped with proprietary communication protocol and firmware, and that evaluating their outdoor units as OUWNMs renders these controls and advancements completely useless. (*Id.*) Mitsubishi requested that either communicating variable-speed systems be exempted from the OUWNM provisions, or that specific allowances be considered to enable communicating variable-capacity outdoor units to be tested in a way that demonstrates compliance with Federal efficiency minimum standards. (*Id.*)

DOE clarifies that the OUWNM requirements will apply to all split-system CAC/HPs units, whether they use proprietary controls to communicate conditioned-space temperature and/or humidity, use a generic thermostat, or allow either installation approach. Also, DOE understands that many ductless multi-split systems and VRF systems are variable-speed systems that employ software that requires the outdoor unit to be paired with a recognized indoor unit (*i.e.,* a pairing confirming system).[41] Manufacturers of ductless multi-split systems and VRF systems may already have the means to test these systems with a generic indoor unit or may need to reprogram their outdoor units to allow operation with a generic indoor unit, for units using a refrigerant with GWP greater than 700 that are manufactured after January 1, 2025. While the latter option may require additional software rework, this reprogramming would require limited engineering hours to implement, such that DOE does not consider it to be burdensome to manufacturers. In response to GE's proposal to allow outdoor-unit-only listings for such systems based on the lowest-performing system combination for the outdoor coil, and Mitsubishi's request for such systems to be exempted from the OUWNM provisions or given special

[40] These instructions are also included in sections 5.1.6.2 and 5.1.6.3 of AHRI 210/240–2024 and AHRI 1600–2024.

[41] While the term used by commenters to refer to such systems is ''communicating,'' DOE notes that the current test procedure uses this term differently. Specifically, ''communicating,'' per the current test procedure, refers to the ability of the system to communicate in-space temperature with both the outdoor and indoor units, instead of communication between the indoor and outdoor units. DOE also notes that neither the AHRI test standards (210/240 and 1600) nor the test procedure being finalized in this rule use the term ''communicating.'' To prevent confusion, DOE is referring to these systems as ''pairing confirming systems.''

allowances, DOE notes that neither approach provides confirmation that a given outdoor unit could not be field paired with a nonproprietary indoor unit(s). Therefore, to maintain consistency across all split-system CAC/HPs, irrespective of the control type, DOE is exempting neither pairing confirming variable-speed systems nor variable-speed communicating systems from the OUWNM provisions, nor allowing either category of outdoor units to be rated based on its lowest-performing combination.

(6) Service Coil Definition

GE Appliances and Mitsubishi requested revision to the ''service coil'' definition (*see* 10 CFR appendix M1, section 1.2) to also include integrated indoor blowers within the definition's scope. (GE Appliances, No. 37 at pp. 1–3; Mitsubishi, No. 28 at p. 2)

GE Appliances commented that mini-split, multi-split, and light VRF systems ("DFS systems") have become increasingly popular in the residential air-conditioning market and that these products are significantly different from traditional ducted systems. (GE Appliances, No. 37 at p. 2) GE Appliances noted that indoor units of such systems typically focus on using the smallest space possible and are composed of a tightly integrated blower fan, evaporator coil, and electronics package. (*Id.*) GE Appliances contended that when the coils on these indoor units fail, by far the most cost-effective means of repairing the system is to replace the entire indoor unit, which includes both the coil and the fan. (*Id.*) GE Appliances noted that DOE currently allows for replacement of indoor coils to repair an existing system without a listing of that indoor coil as a part of a system through the service coil provisions of 10 CFR 430 appendix M1, and that these provisions allow service of existing systems using a legacy refrigerant where the system as a whole has been delisted under OUWNM requirements of 10 CFR 429.16(a)(3). (GE Appliances, No. 37 at pp. 1–2) However, GE Appliances noted that the service coil definition explicitly excludes integrated indoor blowers (*Id.*) To account for more recent prevalence of DFS systems in the market since the last refrigerant transition, GE Appliances suggested that DOE amend the definition of "service coil" to include units with integrated fans from the factory. (GE Appliances, No. 37 at p. 3) GE Appliances proposed the following definition for service coil (proposed additions *italicized* and deletions in ~~strikeout~~):

Service coil means an arrangement of refrigerant-to-air heat transfer coil(s), condensate drain pan, sheet metal or plastic parts to direct/route airflow over the coil(s), which may or may not include external cabinetry and/or a cooling mode expansion device.~~,~~ *A service coil may also include a fan if that fan is integrated into the service coil assembly at the factory. A service coil may be* distributed in commerce solely for replacing an uncased coil or cased coil that has already been placed into service, and ~~that has been~~ *must be* labeled "for indoor coil replacement only" on the nameplate and in manufacturer technical and product literature. The model number for any service coil must include some mechanism (*e.g.*, an additional letter or number) for differentiating a service coil from a coil intended for an indoor unit. (GE Appliances, No. 37 at p. 3)

GE Appliances contended that revising the definition of service coil to account for DFS systems is essential to protect consumers who have recently installed DFS systems using R–410A refrigerant and that without these revisions, indoor replacement units to repair DFS systems during their expected useful life may be limited, and consumers may be required to replace entire systems instead of merely components. (*Id.*) GE further commented that if DFS systems are not able to have indoor coil replacements, there is a risk of significant negative consumer sentiment toward DFS systems. (*Id.*)

Mitsubishi asserted that circumstances where full replacement of ductless indoor units would be significantly less costly than field replacement of individual parts would needlessly impact the pocketbooks of homeowners and consume scarce technician labor hours. (Mitsubishi, No. 28 at p. 2) Mitsubishi recommended a carve out or alteration of the current definition of service coil to allow ductless indoor units to be sold for purposes of service, as it would remedy this concern and be better aligned with the EPA Technology Transitions rule and guidance. (*Id.*)

DOE concurs with GE Appliances that mini-split, multi-split, and VRF systems have become more prevalent in the residential air-conditioning market. As noted by GE Appliances, the current service coil definition does not include indoor units that have integrated indoor blowers. DOE also notes that the service coil definition in AHRI 210/240–2024 and AHRI 1600–2024, the industry standards DOE is referencing in this final rule, also do not include integrated indoor blowers within the service coil definition. Both appendix M1 (see section 1.2 of appendix M1) and the AHRI standards define ''indoor unit'', which includes integrated blowers within the definition's scope. The indoor unit definition in Appendix M1 also explicitly notes that a service coil is not an indoor unit. In relevance to the EPA rule, the labelling requirements at 40 CFR 84.58(b) clarify the installation allowances of indoor units. Specifically, 40 CFR 84.58(b) notes that, after January 1, 2025, specified components intended for use with banned refrigerants shall have the label ''For servicing existing equipment only'' attached. Any indoor units that are intended to be used with banned refrigerants (such as R–410A) fall within the scope of specified components and under the aforementioned regulatory provisions under the EPA's rule would need to have this label attached.

As was noted in the previous section of this notice, the CAC/HP definition in 10 CFR 430.2 includes a requirement that indoor units sold alone be rated as part of a combination. Specifically, the definition states ''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).'' Such indoor units may be distributed by indoor coil manufacturers (''ICMs'') which, as defined in Appendix M1, manufacture indoor units but do not manufacture single-package units or outdoor units. They may also be distributed in commerce alone and not as part of a combination by non-ICMs for the replacement market. For an indoor unit intended only for replacement in an existing system and which is no longer distributed in commerce for installation as a combination, as would be the case for an existing system that uses a refrigerant banned by EPA, the requirement in table 1 of 10 CFR 429.16(a) for the indoor unit to be rated as part of a system would still apply even though the indoor unit is no longer being distributed in commerce as part of a combination. This rating requirement would apply regardless of whether the manufacturer of the indoor unit is an ICM. If the indoor unit uses a refrigerant allowed by EPA only for component replacement (*e.g.,* R–410A), the rating for such a unit would be based on a combination using that refrigerant, and per EPA regulations could not be distributed in commerce as a combination. However, this does not imply that the indoor unit cannot be rated, nor that the entire system would have to be replaced, as suggested by GE. DOE notes further that any such rating

for the indoor unit must be compliant with current standards, and that any indoor units distributed in commerce for use in a system that uses a refrigerant subject to the EPA ban would need to have been certified to DOE as compliant with the applicable standards as part of a combination before January 1, 2025.

(7) Space-Constrained Systems

NCP commented that it performed analysis, testing, and simulations of through-the-wall space-constrained R–410A systems to evaluate available options to meet the proposed OUWNM requirement for applicable outdoor condensing units. (NCP, No. 27 at p. 2) NCP contended that the results of this testing [42] indicated that its space-constrained outdoor condensing units would not meet applicable minimum efficiency requirements when rated using a generic indoor coil as specified by the OUWNM requirements. (*Id.*) NCP asserted that it was not aware of any space-constrained outdoor condensing units from other manufacturers that could meet efficiency requirements when rated as an OUWNM. (*Id.*) NCP asserted that the OUWNM requirements in DOE's proposed rule would effectively prohibit any space-constrained R–410A outdoor condensing unit after January 1, 2026, and leave manufacturers with stranded inventory. (NCP, No. 27 at p. 2) NCP contended that occupants of multifamily housing units with recently installed space-constrained R–410A split systems would be left without options for service replacement of their outdoor condensing unit section, beyond installation of the entire indoor and outdoor split system. (*Id.*) To provide relief from excessive cost burdens, NCP suggested that DOE should include language in the final rule that coil-only ratings for space-constrained split-system outdoor units with R–410A are permissible until January 1, 2028, for units manufactured before January 1, 2025. (*Id.*) Alternatively, NCP suggested that DOE should use its enforcement discretion to provide additional 2-year sell through before OUWNM ratings are required for through-the-wall space-constrained R–410A outdoor condensing units. (*Id.*)

DOE reviewed the confidential data provided by NCP for select outdoor unit models and agrees that the data suggests that these models cannot meet applicable minimum efficiency requirements when tested as OUWNMs. However, DOE notes that the data provided does not include performance data or estimates for designs with any technology improvements, *e.g.,* two-stage or variable-speed compressors. Thus it is not clear that compliance with Federal standards is impossible for space-constrained OUWNMs.

DOE further notes that NCP suggests a delay of the OUWNM requirement until January 1, 2028, but the need for replacement outdoor units would still exist after January 1, 2028, only 3 years after EPA's transition date for R–410A. This would suggest that NCP believes that space-constrained outdoor unit designs can be developed to be compliant with standards using the OUWNM test requirements starting on that date. Regarding stranded inventory, as clarified earlier in section III.E.6.c.1, DOE notes that the EPA rule includes a 1-year sell-through period that would enable any accumulated inventory to be distributed, beyond which any space-constrained CAC/HP outdoor units using R–410A would need to certify as OUWNMs. As discussed elsewhere in this final rule, to the extent that units are distributed in commerce as OUWNMs, they would be distributed as a different basic model as compared to distribution in commerce when paired with an indoor unit.

For these reasons, DOE has determined that there is not sufficient justification for delaying the OUWNM requirements for R–410A space-constrained CAC/HP products. Additionally, as discussed previously in this section, the timing of permitted installations of R–410A systems and components is based on EPA's refrigerant regulations. DOE is clarifying the applicability of the test procedure requirements in this final rule to allow for component installations consistent with EPA's requirements.

(8) Representativeness of Paired Indoor Coil

Rheem questioned the appropriateness of the indoor coil specifications currently required for OUWNM testing. (Rheem, No. 34 at pp. 2–3) Rheem provided historical background of DOE's OUWNM provisions by citing language from past rulemaking notices, noting some of the following key points:

(1) DOE first proposed an NGIFS for rating and certifying the performance of outdoor units designed for R–22 in the November 9, 2015 SNOPR, where DOE proposed an upper limit on NGIFS equal to 1.15. 80 FR 69278, 69404.

(2) DOE indicated that its analysis supporting NGIFS values for OUWNM testing was based on reverse-engineered SEER 13 split systems (blower-coil combinations) designed for R–22. 81 FR 36992, 37010.

(3) However, DOE set the upper limit on NGIFS at 1.0 in the June 08, 2016 Final Rule, arguing that a lower NGIFS better reflected the installed base of indoor units, since the installed base also included 10 SEER split systems. 81 FR 36992, 37010.

(4) In the August 24, 2016 SNOPR, DOE acknowledged that legacy (existing) indoor units matched with no-match outdoor units would not always be indoor units designed for R–22, and that the NGIFS 1.0 upper limit did not provide a good representation of the heat transfer performance of indoor coils with newer designs. 81 FR 58164.

Rheem also commented on the DOE proposal in the August 8, 2016 SNOPR to adopt a maximum NGIFS requirement generally for testing of single-split coil-only systems. Because this proposal did not address OUWNM outdoor units and because DOE did not adopt the proposal, Rheem stated that it is not relevant to the OUWNM discussion. Based on the historical context provided from prior rules, Rheem requested DOE review the test provisions for OUWNMs, the definition of NGIFS, and its upper limit to accurately represent the current installed base of indoor coils with which such condensing units would be matched in the field. (Rheem, No. 34 at p. 3)

DOE appreciates Rheem's comment charting the historical development of the OUWNM testing provisions. As noted earlier in section III.E.7 and indicated by Rheem's comment, the current instruction at section 2.2.e of appendix M1 requires that an OUWNM be tested using a coil-only indoor unit coil that has round tubes of outer diameter no less than 0.375 inches and NGIFS of no greater than 1.0 sq in/Btu/hr. These indoor coil specifications were initially finalized for appendix M in the June 8, 2016 Final Rule and extended to appendix M1 in the January 2017 Final Rule. 81 FR 36992, 82 FR 1426. DOE did not propose revision of the requirements in the April 2024 NOPR.

In response to Rheem's comment, DOE reviewed historical data, starting with shipments analysis supporting the energy conservation standards direct final rule published on January 6, 2017 (''January 2017 DFR''). 82 FR 1786. DOE conducted analysis to determine whether a substantial percentage of CAC system replacements in 2025 would occur in residences in which the indoor unit would have been installed prior to 2010, *i.e.,* when the representative indoor unit would have been part of a

[42] NCP shared results of its analysis in confidential exhibits A and B.

13 SEER R–22 system, consistent with DOE's initial analysis to establish the NGIFS requirements. To conduct this analysis, DOE used national impact analysis results provided in the January 2017 DFR and its supporting documents and spreadsheets. (*See* 82 FR 1786, 1822–1824) In this assessment, DOE considered that a portion of system replacements have been outdoor-unit-only installations, consistent with the January 2017 DFR assumptions for the percentage of installations involving just an outdoor unit. This factor increases the average age of an existing indoor unit, since, for some portion of the existing residences, the indoor unit would not have been replaced during the last outdoor unit replacement.

The results of this analysis indicate that more than 60 percent of system replacements in 2025 would involve a residence where the indoor unit was installed before 2010. DOE also considered sensitivity of this analysis to differences between shipment projections made to support the January 2017 DFR and actual recent-year shipments and found that an analysis updated for recent shipment data would suggest a slightly higher percentage for pre-2010 indoor units. Thus, DOE concludes that the NGIFS limit initially established in the June 8, 2016 Final Rule is still representative, and DOE is not revising it in this final rule.

(9) Single Cooling Air Volume Rate

AHRI, the CA IOUs, Carrier, and Daikin recommended that DOE retain the requirement to test OUWNMs with a single cooling air volume rate. (AHRI, No. 25 at p. 5; CA IOUs, No. 32 at pp. 2–3; Carrier, No. 29 at p. 4; Daikin, No. 36 at p. 2)

AHRI recommended that the testing instructions proposed for OUWNMs at section 4.2 of appendix M1 also include the current regulatory requirement that the coil-only indoor unit has a ''single cooling air volume rate.'' (AHRI, No. 25 at p. 5) The CA IOUs also recommended that DOE retain the requirement for testing OUWNMs with a ''single cooling air volume rate'' in section 4.2 of the proposed revision to appendix M1 and include an identical requirement in section 3.2 of appendix M2. (CA IOUs, No. 32 at p. 2) The CA IOUs commented that they believe this specific requirement of a single cooling air volume rate was inadvertently left out of the new AHRI standards. (*Id.*) The CA IOUs reasoned that because OUWNMs are compatible with any existing air handler that continues to remain as the primary air-moving system after the originally paired outdoor unit is replaced, DOE cannot guarantee that such systems will have controls capable of varying airflow during operation and should, therefore, continue to require a single air volume rate. (*Id.*) Carrier also noted that the current appendix M1 requirements for OUWNM testing require a single cooling air volume rate, and it recommended that DOE continue to require a single cooling air volume rate. (Carrier, No. 29 at p. 4) Daikin strongly suggested that DOE maintain the single airflow rate requirement for all OUWNMs, reasoning that OUWNMs do not include an indoor unit change and would, therefore, not have any enhancements, such as non-bleed expansion valves or blower delays, to improve cyclic performance. (Daikin, No. 36 at p. 2)

The current requirements at section 2.2e of appendix M1 require that an OUWNM be tested using a coil-only indoor unit at a single cooling air volume rate. DOE notes that this requirement was inadvertently left out of the April 2024 NOPR. DOE agrees with the reasoning presented by commenters advocating that this requirement be retained. Therefore, DOE is including language at section 4.2 of revised appendix M1 and section 3.2 of new appendix M2, requiring the use of a single cooling air volume rate when testing OUWNMs.

(10) Use of Default Degradation Coefficient for OUWNM Testing

AHRI, the CA IOUs, and Daikin recommended that DOE use the default degradation coefficient of 0.25 for all OUWNMs, for both heating and cooling modes. (AHRI, No. 25 at p. 5; CA IOUs, No. 32 at p. 3; Daikin, No. 36 at p. 2)

AHRI noted that the existing provisions for OUWNMs for degradation coefficient in enforcement is to use the default value (0.25), whereas the published versions of AHRI 210/240–2024 and AHRI 1600–2024 allow for testing of CD for OUWNMs. (AHRI, No. 25 at p. 5) AHRI strongly recommended that DOE adopt the default degradation coefficient of 0.25 for all OUWNMs, for both heating and cooling modes. (*Id.*) AHRI reasoned that a significant portion of OUWNM units are applied in multifamily apartment dwelling situations, where the probability of being properly paired with an indoor product that can be retrofitted to have a time delay, or having an indoor product that is retrofitted with a non-bleed thermal expansion valve or an electronic expansion valve is relatively low (since many multifamily apartment dwelling indoor systems are ceiling-mount blower coil systems or wall-mount blower coil systems). (*Id.*) Therefore, AHRI contended that a substantial portion of OUWNMs installed in multifamily applications would not have the lower CD in the real world, as experienced in testing. (*Id.*) The CA IOUs also suggested that the cyclic degradation default values in proposed appendices M1 and M2 align with the current requirement in 10 CFR part 429 for OUWNMs. (CA IOUs, No. 32 at p. 3) The CA IOUs noted that they supported the use of default values because the metering device, which is unknown for an OUWNM, significantly affects cyclic degradation. (*Id.*) Daikin also suggested that the default value of 0.25 be used for both cooling and heating degradation coefficients for OUWNMs. (Daikin, No. 36 at p. 2)

As noted by commenters, the current enforcement requirement at 10 CFR 429.134(k)(2)(ii) states that DOE will use the default cooling and heating degradation coefficients when testing models of OUWNMs. DOE agrees with the reasoning presented by commenters and notes that this enforcement requirement was put in place on the basis of the same rationale. Additionally, the requirement was intended to be adopted broadly for testing, not just for enforcement, as indicated in the June 2016 Test Procedure Final Rule. 81 FR 36992, 37011. To clarify that this requirement also applies to testing, DOE is including provisions at section 4.2 of revised appendix M1 and section 3.2 of new appendix M2 to require that testing of OUWNMs only use the default degradation coefficients (0.25) for both cooling and heating modes.

8. Inlet and Outlet Duct Configurations

Both appendix D of the AHRI 210/240–202X Draft and appendix D of the AHRI 1600–202X Draft define lists of clarifications/exceptions to their referenced version of ASHRAE Test Standard 37 (ANSI/ASHRAE 37–2009). These clarifications/exceptions have been revised repeatedly throughout the version history of the AHRI 210/240 standard. In the April 2024 NOPR, DOE noted that both appendix D of AHRI 210/240–202X Draft and appendix D of AHRI 1600–202X Draft contain updates regarding inlet and outlet duct configurations, including the duct revisions investigated in RP 1581 and RP 1743 to accommodate smaller environmental chambers. These updates are consistent with the draft of an update of ANSI/ASHRAE Standard 37 (''May 2023 ASHRAE 37 Draft''). DOE surmised that the inclusion of these May 2023 ASHRAE 37 Draft updates in appendix D of the relevant AHRI drafts represented industry consensus, and DOE tentatively determined that the

updates are appropriate for CAC/HP testing. 89 FR 24206, 24231. Consequently, DOE proposed 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. *Id.*

DOE noted 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 had not yet been finalized and published. *Id.* DOE further noted 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. *Id.*

DOE did not receive any comments regarding the aforementioned proposals in the April 2024 NOPR. AHRI 210/240–2024 and AHRI 1600–2024 finalized the updates regarding inlet and outlet duct configurations without substantial change. Both standards continue to reference ANSI/ASHRAE 37–2009 since the May 2023 ASHRAE 37 Draft has not yet been finalized. Therefore, consistent with the April 2024 NOPR proposal, DOE is incorporating by reference Appendix D of AHRI 210/240–2024 and AHRI 1600–2024, at appendix M1 and appendix M2, respectively. DOE is also continuing to maintain reference to ANSI/ASHRAE 37–2009 since the May 2023 ASHRAE 37 Draft has not yet been finalized.

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).

In the April 2024 NOPR, DOE noted that 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. 89 FR 24206, 24231. DOE noted that AHRI 210/240–202X Draft and AHRI 1600–202X Draft specify additional steps for calculating the HSPF2 and SHORE of heat pumps having a variable-capacity compressor and a heat comfort controller and that these additional steps are similar to the additional steps for calculating the HSPF2 and SHORE of other system types having a heat comfort controller. *Id.* DOE 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 representative measures of unit operation when installed with heat comfort controllers. *Id.* Therefore, DOE proposed 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. *Id.* Likewise, DOE proposed 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. *Id.*

DOE did not receive any comments regarding these proposals. AHRI 210/240–2024 and AHRI 1600–2024 finalized the updates to the heat comfort controller calculations without substantial change. Therefore, consistent with the April 2024 NOPR proposals, DOE is incorporating by reference section 11.2.2.5 of AHRI 210/240–2024 and AHRI 1600–2024, at appendix M1 and appendix M2, respectively.

F. 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 in terms of the efficiency metrics SCORE and SHORE in appendix M2. As previously explained, these long-term revisions would be implemented at the new appendix M2 via incorporation by reference of the relevant industry consensus test procedure, AHRI 1600–2024. DOE has reviewed AHRI 1600–2024 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)(3)) 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.

1. Power Consumption of Auxiliary Components

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 are seasonal efficiency metrics that don't include all energy consumed by the systems, these new metrics do address energy use of all components and operational modes, specifically including the standby and off mode power consumption of auxiliary components. These include 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.

SEER2 and HSPF2 are both ratio metrics that include all calculated space conditioning in the numerator and all energy use associated with space conditioning in the denominator. In contrast, AHRI 1600–202X Draft includes two new quantities—$E_{s,c}$ (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 hours, as applicable), and $E_{s,h}$ (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 hours, as applicable). Table 14 and table 16 of AHRI 1600–202X Draft outline instructions for determining each component's number of standby power operating hours in cooling mode and heating modes, and appendix G of AHRI 1600–202X Draft [43] outlines instructions for determining the average power of all auxiliary components considered in the calculations of either $E_{s,c}$ or $E_{s,h}$.

In the April 2024 NOPR, DOE tentatively concluded 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. 89 FR 24206, 24236. DOE 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. *Id.* Therefore, DOE proposed to incorporate by reference the new cooling and heating performance metrics, SCORE and SHORE, as

[43] In the April 2024 NOPR, DOE incorrectly referred to appendix H of AHRI 1600–202X Draft as the appendix regarding the determination of average power of auxiliary components (*see* 89 FR 24206, 24236). This was a typographical error, since the appendix regarding the determination of average power of auxiliary components is at appendix G of AHRI 1600–202X Draft.

included in AHRI 1600–202X Draft, and the associated provisions regarding the standby and off mode power consumption of auxiliary components, in appendix M2. *Id.*

DOE did not receive any comments regarding this proposal. AHRI 1600–2024 finalized the new cooling and heating performance metrics, SCORE and SHORE, and the associated provisions regarding the standby and off mode power consumption of auxiliary components, without substantial change. Therefore, consistent with the April 2024 NOPR proposal, DOE is incorporating by reference AHRI 1600–2024, and adopting the SCORE and SHORE metrics, and the associated provisions regarding the standby and off mode power consumption of auxiliary components, at appendix M2.

2. Impact of Defrost on Performance

In order for HPs to undergo a defrost cycle, which aims to remove the moisture collected as frost on the outdoor coil, an HP temporarily switches to cooling mode operation. This enables an HP to transfer heat from the indoor coil to the outdoor coil, thus providing the heat needed to warm the coil above freezing temperature and melt the frost.

In the April 2024 NOPR, DOE explained how AHRI 1600–202X Draft introduces two changes to the treatment of defrost performance of CAC/HPs: (1) it simplifies the demand defrost credit by uniformly applying a 3-percent increase to the SHORE rating for all HPs equipped with demand defrost, and (2) it accounts for the use of supplementary heat during defrost using a new defrost heat and defrost overrun debits. 89 FR 24206, 24236–24238. DOE surmised that AHRI 1600–202X Draft's introduction of the simplified demand defrost credit in AHRI 1600–202X Draft represented 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. 89 FR 24206, 24237. DOE 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. Similarly, DOE tentatively determined that the defrost heat and defrost overrun debits associated with accounting for use of supplementary heat during defrost represented industry consensus and that these debits result in more representative CAC/HP efficiencies for models with supplementary heat during defrost. Therefore, DOE proposed to incorporate by reference at appendix M2 the defrost-related provisions from AHRI 1600–202X Draft.

In response to DOE's proposal, the Joint Advocates stated that they acknowledge the improvements made to the treatment of defrost in the proposed appendix M2. (Joint Advocates, No. 30 at p. 4) However, the Joint Advocates also commented that, by assigning the defrost credit and debits based on a yes or no framework, the proposed appendix M2 does not capture the true differentiation that exists between defrost controls. (*Id.*) The Joint Advocates encouraged DOE to collect information about defrost mechanisms and consider how defrost impact may be better represented in a future update to the CAC/HP Federal test procedures. (*Id.*)

In response to the Joint Advocates, DOE notes that it will continue to review the defrost credit and debits and may propose changes once more information is made available. However, since little or no information is currently available and the defrost credit and debits represent industry consensus, DOE is adopting the defrost credit and debits without modification, as proposed.

DOE did not receive any other comments regarding this proposal. AHRI 1600–2024 finalized the defrost related provisions discussed in the aforementioned paragraphs, without substantial change. Therefore, consistent with the April 2024 NOPR proposal, DOE is incorporating by reference AHRI 1600–2024 and adopting the defrost-related provisions at appendix M2.

3. Updates to Building Load Lines and Temperature Bin Hours

In the April 2024 NOPR, DOE discussed several changes introduced in AHRI 1600–202X Draft with regard to the building load lines and temperature bin hours used when determining the new seasonal metrics, SCORE and SHORE. 89 FR 24206, 24238–24239. Specifically, DOE noted that (1) the new metrics use total hours instead of fractional hours; (2) total hours are split into conditioning hours and shoulder hours, with the cooling conditioning hours and cooling-season shoulder hours for each bin listed in table 15 of AHRI 1600–202X Draft [44] and the heating conditioning hours and heating-season shoulder hours for each bin listed in table 18 of AHRI 1600–202X Draft; [45] and (3) the cooling and heating building load lines were revised based on PNNL EnergyPlus simulations. *Id.*

DOE surmised 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 represented industry consensus for calculations of the new cooling and heating performance metrics, SCORE and SHORE. 89 FR 24206, 24239. DOE proposed 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 AHRI 1600–202X Draft, at appendix M2. *Id.*

In response to DOE's proposal, Copeland asserted that, while a differentiated load line for variable-speed systems is indeed consistent with AHRI 1600–2024, it may no longer be representative of how various compressor-staging technologies are sized and installed in the field by the time ratings in terms of SCORE and SHORE take effect. (Copeland, No. 31 at pp. 2–3) Copeland pointed to a recent (February 2024) revision of the capacity range sizing recommendations for two-stage systems in the third edition of Air Conditioning Contractors of America's (''ACCA's'') Manual S® [46] as the source of its concern, remarking that these revisions were not available when the AHRI Standards Technical Committee discussions regarding AHRI 210/240–2024 and AHRI 1600–2024 took place. (*Id.*)

Copeland also noted that the slope factors used to differentiate the heating building load line for variable-speed HPs from single-stage and two-stage HPs in the current appendix M1 (*i.e.,* C and C_{VS}) were derived from an Oak Ridge National Laboratory (''ORNL'') analysis [47] and influenced by the capacity range sizing recommendations in the second edition of ACCA's Manual S. (Copeland, No. 31 at pp. 2–3) Copeland commented that the second

[44] In the relevant April 2024 NOPR preamble discussion, there were instances where DOE mistakenly referred to section table 13 of AHRI 1600–202X Draft. This has been corrected to table 15 of AHRI 1600–202X Draft in this final rule preamble discussion.

[45] In the relevant April 2024 NOPR preamble discussion, there were instances where DOE mistakenly referred to table 15 of AHRI 1600–202X Draft. This has been corrected to table 18 of AHRI 1600–202X Draft in this final rule preamble discussion.

[46] To access the normative section of the third edition of the ACCA Manual S, *see www.acca.org/standards/technical-manuals/manual-s.*

[47] *See www.regulations.gov/document/EERE-2016-BT-TP-0029-0002.*

edition of ACCA's Manual S allowed a range of capacity from 0.9 to 1.15 for single-stage and two-stage HPs and 0.9 to 1.3 for variable-speed HPs, which, if used to calculate a size adjustment factor for variable-speed HPs, equals 1.07 (by dividing (0.9 + 1.3) by (0.9 + 1.15)). (*Id.*) Taking this same approach with the third edition of ACCA's Manual S, which allows oversizing for two-stage HPs up to 1.25 and up to 1.3 for variable-speed HPs, Copeland stated that the size adjustment factor for variable-speed HPs would be 1.02 (by dividing (0.9 + 1.3) by (0.9 + 1.25)) instead of 1.07. (*Id.*)

Rather than adjusting the values of C and C_{VS}, however, Copeland encouraged DOE to consider eliminating the differentiated load line altogether, since a building's load calculation is not dependent on the compression technology of a heating and/or cooling system. (Copeland, No. 31 at pp. 2–3) Copeland also commented that it could not find any field data to support the idea that technicians vary oversizing practices based on compression technologies. Copeland asserted it is more likely that technicians calculate the load of the building and then select the next-larger capacity an OEM has available in a good, better, best offering when presenting quotes to homeowners. (*Id.*)

In response to Copeland's comment encouraging DOE to consider eliminating the differentiated load line altogether, DOE notes that similar concerns were raised and addressed in the previous CAC/HP final rule, published by DOE on January 5, 2017 (''January 2017 Final Rule''). 82 FR 1426. In the January 2017 Final Rule, DOE noted that the incorporation of differentiated slope factors does not suggest any difference in building load when using different technology. 82 FR 1426, 1456. Rather, the slope factor simply represents the ratio of building load to heat pump capacity. *Id.* DOE acknowledged that variable-speed products are slightly more oversized in comparison to the building heating load than are single-speed and two-stage products. *Id.* Keeping the building load constant and increasing the variable-speed HP capacity reduces the building load/capacity ratio; hence DOE selected a lower slope factor (*i.e.,* C_{VS}, equal to 1.07) for variable-speed HPs as compared to the slope factor for single-stage and two-stage HPs (*i.e.,* C, equal to 1.15). *Id.* In the absence of robust data showing average load/capacity ratios for different products, DOE based its building load factors on ACCA's Manual S recommendations, at the time using the second edition. The topic of a differentiated building load line for variable-speed units was also discussed during the development of the AHRI 210/240 and 1600 standards, and consensus was formed that it was appropriate to retain the differentiated line. Notably, both AHRI 210/240–2024 and AHRI 1600–2024 include a differentiated building load line for variable-speed units.

In response to Copeland's comment, DOE notes that additional changes to the capacity range sizing recommendations were made in the third edition of ACCA's Manual S that were not mentioned in Copeland's comment. Specifically, the minimum capacity factor recommended for variable-speed heat pumps was increased from 0.9 in the second edition of ACCA's Manual S to 1.0 in the third edition of ACCA's Manual S.[48] Incorporating this change into the approach taken by Copeland (as described in the preceding paragraphs), the size adjustment factor for variable-speed HPs as compared with two-stage heat pumps would remain 1.07 (by dividing (1 + 1.3) by (0.9 + 1.25)). DOE agrees that a future revisit of these issues, taking into consideration the revision to Manual S and any new data that could be collected to shed light on potential sizing differences, and allowing for a robust discussion of the issues among relevant stakeholders, may be appropriate when the AHRI test standards and DOE test procedure undergo amendments in future. However, DOE notes the committee consensus for retaining the 1.07 factor in the test standards, as reflected in AHRI 1600–2024, and is finalizing the DOE test procedure with this factor in this document.

AHRI 1600–2024 finalized the updates to the building load lines and temperature bin hours, without substantial change from AHRI 1600–202X Draft. Therefore, consistent with the April 2024 NOPR proposal, DOE is incorporating by reference AHRI 1600–2024 and adopting the associated building load lines and temperature bin hours, 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 18 of AHRI 1600–2024 are optional.

[48] *See* table N1.16.2.4 in the normative section of the third edition of ACCA's Manual S, available here: *www.acca.org/standards/technical-manuals/manual-s.*

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/HP combinations do not include a designated air mover to circulate air, the DOE test procedures prescribe default values for power input and heat output to represent the furnace fan with which the indoor coil would be paired in a field installation. The default values are equal to the measured airflow rate (in scfm) multiplied by a defined coefficient (expressed in Watts (''W'') per 1,000 scfm (''W/1,000 scfm'') for fan power, and Btu/h per 1,000 scfm (''Btu/h/1,000 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).[49] *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/1,000 scfm and a default fan heat coefficient of 1,385 Btu/h/1,000 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/1,000 scfm and a default fan heat coefficient of 1,505 Btu/h/1,000

[49] 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).

scfm. *See, e.g.,* appendix M1, section 3.3.e.

In addition to the aforementioned default fan powers for single-stage coil-only systems, which reflect full-load operation, appendix M1 defines lower-load default fan powers at a reduced air volume rate of 75 percent for two-stage and variable-speed coil-only systems. Appendix M1 then uses these full-load and lower-load default fan powers to interpolate 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).

In the April 2024 NOPR, DOE noted that AHRI 1600–202X Draft defines revised lower-load default fan powers at a reduced air volume rate of 65 percent (rather than 75 percent) for two-stage and variable-speed coil-only systems and 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). 89 FR 24206, 24239–24240. AHRI 1600–202X Draft also moves mobile home systems from the default fan power coefficient equation for space-constrained systems to the equation for ''conventional'' non-space-constrained systems, because insufficient evidence was presented to the AHRI Standards Technical Committee to justify that default fan power coefficients for mobile home systems should be different from ''conventional'' systems. Therefore, solely for space-constrained coil-only systems, 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 (''$DFPC_{SC}$''). 89 FR 24206, 24239–24240. 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 in the default fan power coefficient interpolation (''$DFPC_{NSC}$''). *Id.* All default fan powers are lower than those used in the calculation of $DFPC_{MHSC}$ and $DFPC_{C}$ in appendix M1.

DOE surmised 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 represented 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 paired in a field installation. *Id.* DOE tentatively determined that the reduced full-load and low-load default fan powers more accurately reflected 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). *Id.* DOE also tentatively determined that the reduced air volume rate more accurately reflected the average low-load air volume rate of the currently installed base for blowers paired with coil-only CAC/HP installations. *Id.* Therefore, DOE proposed 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. *Id.*

DOE did not receive any comments regarding this proposal. AHRI 1600–2024 finalized the changes to the default fan power coefficients for coil-only systems, without change. Therefore, consistent with the April 2024 NOPR proposal, DOE is incorporating by reference AHRI 1600–2024 and the associated provisions for default fan power coefficients, at appendix M2.

5. Airflow Limits To Address Inadequate Dehumidification

In the April 2024 NOPR, DOE explained that, to address adequate dehumidification in hot and warm, humid climates, AHRI 1600–202X Draft established new airflow limits for the cooling mode tests to avoid high sensible heat ratios. 89 FR 24206, 24240. Specifically, section 6.1.5.2 of AHRI 1600–202X Draft sets a maximum airflow limit at 37.5 scfm per 1000 Btu/h (*i.e.,* 450 cubic feet per minute (''cfm'') per ton of capacity) for cooling full airflow. *Id.* Additionally, section 6.1.5.3 of AHRI 1600–202X Draft sets a maximum airflow limit at 50 scfm per 1,000 Btu/h (*i.e.,* 600 cfm per ton of capacity) for cooling low airflow. *Id.* Should the cooling full airflow or cooling low airflow specified by the manufacturer exceed these limits, AHRI 1600–202X Draft requires that airflows be reduced to meet these limits for testing. *Id.*

In the April 2024 NOPR, DOE surmised that the addition and selection of specific cooling airflow limits in AHRI 1600–202X Draft represented industry consensus regarding the issue of inadequate dehumidification. 89 FR 24206, 24240. DOE tentatively determined that such airflow limits were appropriate to ensure that CAC/HPs provide adequate dehumidification during cooling mode operation and, therefore, DOE proposed to incorporate by reference the cooling full airflow and cooling low airflow limits specified in the AHRI 1600–202X Draft, at appendix M2. *Id.*

DOE did not receive any comments regarding this proposal. AHRI 1600–2024 finalized the cooling full airflow and cooling low airflow limits without change. Therefore, consistent with the April 2024 NOPR, DOE is incorporating by reference AHRI 1600–2024 and the associated airflow limits at appendix M2.

G. General Comments Received in Response to the April 2024 NOPR

In response to the April 2024 NOPR, DOE received several general comments not specific to any one test procedure provision. This section discusses those general comments received.

The Joint Advocates commented that before appendix M2 is enforced, DOE should encourage manufacturers to optionally rate their systems using SCORE and SHORE, *i.e.,* the appendix M2 energy efficiency metrics. (Joint Advocates, No. 30 at p. 1) The Joint Advocates commented that such ratings would allow DOE to do an appropriate crosswalk from SEER2 to SCORE, and HSPF2 to SHORE, to support the next round of CAC/HP standards rulemaking. (*Id.*) As discussed in section II of this document, 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. However,

manufacturers may choose to make optional representations based on the metrics in appendix M2 and are encouraged to provide any test data to DOE to help support an analysis of the crosswalk of the energy efficiency metrics from appendix M1 to appendix M2.

Additionally, the Joint Advocates commented that the bin method used to calculate HSPF2 and SHORE assumes that an HP will provide as much capacity as possible and resistance heat will meet the remaining building load. (Joint Advocates, No. 30 at p. 4) However, the Joint Advocates asserted that control logic will ultimately determine the relative operation of these heat sources, which may not fit with the bin calculation method assumption described. (*Id.*) The Joint Advocates stated that, in the case that an HP uses more resistance heat than assumed by the bin calculation method, a lower efficiency would be observed in the field than the efficiency rated for an HP; subsequently, the Joint Advocates encouraged DOE to consider this aspect of the CAC/HP Federal test procedure in a future rulemaking. (*Id.*)

In response to the Joint Advocates' comment, at this time DOE has not determined an approach to account for the controls of the heat pump working in tandem with electric resistance heat, and is not adopting such an approach in this final rule. DOE notes that it may consider such an approach in the future.

H. Represented Values

In the following sections, DOE discusses requirements regarding represented values. To the extent that DOE is amending the requirements specified in 10 CFR part 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 this final rule. Prior to 180 days after publication in the **Federal Register** of this 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 this test procedure final rule.

1. 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), cooling capacities, and estimates for cooling load hours (''CLH'') and heating load hours (''HLH'') in a year. CLH and HLH can be thought of as the hours of run time at full capacity required to provide seasonal conditioning (in Btu) as calculated in the test procedure to determine seasonal efficiencies. 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.[50]

In the April 2024 NOPR, DOE proposed to retain the current CLH and HLH estimates in appendix M1, for use in conjunction with SEER2 and HSPF2 representations. 89 FR 24206, 24242–24243.

For appendix M2, DOE proposed new estimates for CLH and HLH for use in conjunction with the proposed appendix M2 efficiency metrics, SCORE and SHORE. 89 FR 24206, 24243. DOE noted that 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. *Id.* Therefore, DOE tentatively determined that the proposed appendix M2 required new CLH and HLH values for use by the FTC. *Id.* Specifically, DOE proposed to use 1,457 and 972 hours as estimates for CLH and HLH, respectively, for use in conjunction with SCORE and SHORE representations. *Id.* DOE presented step-by-step derivations of proposed appendix M2 CLH and HLH values in a docketed white paper titled ''Derivation of Proposed Appendix M2 Cooling Load Hours and Heating Load Hours for the Federal Trade Commission.'' [51] *Id.*

In response to DOE's proposal, Keith Rice requested that the basis for these revised cooling and heating load hours (and the revised building load lines and temperature bin hours, discussed in section III.F.3 of this final rule) be well documented in a published report. (Keith Rice, No. 33 at p. 1) Keith Rice commented that this is important considering that the proposed CLH and HLH values for appendix M2 give a much higher weighting to cooling energy use performance relative to heating. (*Id.*)

In response to Keith Rice, DOE notes that the CLH and HLH values presented in its docketed white paper were derived from the building load lines and temperature bin hours presented in AHRI 1600–202X Draft. Therefore, the report requested by Keith Rice (*i.e.,* a report detailing the basis for the revised building load lines and temperature bin hours in AHRI 1600–2024) would need to be provided by AHRI. DOE understands the value of publicizing the weather analysis that forms the basis of the building load lines and temperature bin hours under appendix M2. Subsequently, DOE is willing to support AHRI in the process of publicizing a weather analysis report, as requested by Keith Rice.

DOE did not receive any other comments regarding the proposal for new CLH and HLH values under appendix M2. Therefore, for the reasons discussed in the preceding paragraphs and the April 2024 NOPR, DOE is adopting different CLH and HLH values under appendix M2 than under the current appendix M1, as proposed.

In response to DOE's proposals for CLH and HLH, Keith Rice also commented on the proposed calculations of annual operating costs in the April 2024 NOPR. (Keith Rice, No. 33 at p. 1) Keith Rice noted that the calculations of annual operating costs for single- versus variable-speed HPs in the current appendix M1 and proposed appendix M2 give a 7-percent additional energy savings benefit to variable-speed systems when compared on an equal rated capacity basis. (*Id.*) Keith Rice recommended, reasoning that consumers would expect that operating cost comparisons would be on the basis of equal house loads, that the existing appendix M1 and proposed appendix M2 operating cost calculation approaches be modified to remove the extra 7-percent benefit. (*Id.*) Keith Rice commented that, in the current appendix M1 and proposed appendix M2, the seasonal energy performance factors (*i.e.,* SEER2 and HSPF2 for appendix M1 and SCORE and SHORE for appendix M2) for variable-speed systems have already been boosted by the assumption of lower cooling and heating building loads for a given cooling capacity. (*Id.* at pp. 1–2) Subsequently, Keith Rice suggested that the V-factor of 0.93 in cooling mode and the lower 1.07 C_x factor in heating mode be removed from the operating cost calculations for energy labeling so as to not result in a type of double counting

[50] *See* table 21 of appendix M1 for the current CLH and HLH estimates used for rating values.

[51] *See* Docket No. EERE–2022–BT–TP–0028–0019.

of energy savings benefits for variable-speed units. (*Id.*)

DOE appreciates Keith Rice's comments regarding the calculations of annual operating costs and understands that, if a variable-speed product is compared with a single- or two-stage product on an apples-to-apples basis (*i.e.,* if both products hypothetically had the same represented cooling capacity and same represented SEER2 or HSPF2 under appendix M1 or SCORE or SHORE under appendix M2), the calculations of annual operating costs for a variable-speed product would yield 7-percent lower results. However, DOE notes that this 7-percent difference has been used by FTC for some time—since it was adopted in the January 2017 Final Rule. 82 FR 1426, 1473–1475. Additionally, DOE notes that this 7-percent difference in annual operating costs is relatively marginal compared to other factors of variability, such as electricity rates, consumer usage patterns, etc. For these reasons, DOE is adopting the calculations of annual operating costs as proposed in the April 2024 NOPR, which are unchanged from the existing calculations of annual operating costs.

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. In the April 2024 NOPR, DOE proposed to incorporate by reference AHRI 210/240–202X Draft at appendix M1, and it noted that section 11.3 and appendix G of AHRI 210/240–202X Draft [52] include the same test instructions to determine $P_{W,OFF}$ as are present in the current appendix M1. 89 FR 24206, 24243. Therefore, DOE proposed no changes in representation requirement for off mode testing when testing per appendix M1. *Id.*

For appendix M2, DOE noted that the applicable metrics, SCORE and SHORE, directly incorporate off mode power consumption and as such, requiring representation of $P_{W,OFF}$ would be redundant for appendix M2. 89 FR 24206, 24243. Therefore, DOE proposed 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. *Id.*

[52] In the April 2024 NOPR preamble discussion, there were instances where DOE mistakenly referred to section 11.2.3 and appendix H of AHRI 210/240–202X Draft. This has been corrected to section 11.3 and appendix G of AHRI 210/240–202X Draft in this final rule preamble discussion.

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. In the April 2024 NOPR, DOE proposed to retain this flexibility for testing to appendix M1. 89 FR 24206, 24243.

For appendix M2, DOE extended 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 to calculate the SCORE and SHORE metrics when testing to appendix M2. 89 FR 24206, 24243. Specifically, DOE proposed 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). *Id.* 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. *Id.*

In response to the April 2024 NOPR, Carrier, Lennox, and Rheem all commented in support of DOE's proposal pertaining to off mode power. (Carrier, No. 29 at p. 5; Lennox, No. 24 at p. 4; Rheem, No. 34 at p. 5) Therefore, for the reasons discussed in the preceding paragraph and the April 2024 NOPR, DOE is adopting these changes as proposed.

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.

In the April 2024 NOPR, to maintain consistency with the existing efficiency metrics, DOE proposed to extend the same tolerance requirement to the new efficiency metrics measured per appendix M2—EER, SCORE and SHORE. 89 FR 24206, 24243.

DOE did not receive any comments regarding this proposal pertaining to AEDM tolerances on the new metrics and, therefore, DOE is adopting the change as proposed.

4. Removal of the AEDM Exception for Split-System CAC/HPs

Currently, the AEDM requirements at 10 CFR 429.70(e) 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).

In the April 2024 NOPR, DOE noted that since amendments proposed in the NOPR are not expected to be finalized and made effective before July 1, 2024, the AEDM exception for non-space-constrained single-split-system CAC/HPs would no longer apply at the time this rulemaking finalizes. 89 FR 24206, 24243. As such, DOE proposed to remove the date-based application of the AEDM requirement and instead clarify 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. *Id.* DOE did not receive any comments regarding this proposal and is adopting the change as proposed.

I. Enforcement Provisions

1. Verifying Cut-Out and Cut-In Temperatures

In the April 2024 NOPR, DOE proposed that for assessment and enforcement testing of HP models, the cut-out and cut-in temperatures may be verified using the test method in appendix J of AHRI 210/240–202X Draft and AHRI 1600–202X Draft, 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. 89 FR 24206, 24243.

AHRI 210/240–2024 and AHRI 1600–2024, the industry standards DOE is referencing in this final rule, finalized the relevant test method for determining cut-out and cut-in temperatures in appendix J without any substantial change. Therefore, consistent with the April 2024 NOPR, DOE is adding product-specific provisions at 10 CFR

429.134(k)—specifically, DOE is adding provisions that for assessment and enforcement testing of HP models, the cut-out and cut-in temperatures may be verified using the method in appendix J of AHRI 210/240–2024 or AHRI 1600–2024, 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.

In response to the April 2024 NOPR, the Joint Advocates encouraged DOE to adopt a requirement for manufacturers to report and certify cut-out and cut-in temperatures for all HPs as part of a separate rulemaking. (Joint Advocates, No. 30 at p. 2) DOE maintains that it will consider certification requirements for CAC/HPs, including the potential requirement for certification of cut-out and cut-in temperatures, in a separate rulemaking, as noted in the April 2024 NOPR. 89 FR 24206, 24243.

Additionally, the Joint Advocates expressed uncertainty regarding whether DOE intended to limit cut-out and cut-in temperature verification to CCHPs, specifically pointing to the following sentence [53] of the April 2024 NOPR preamble: ''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.'' (Joint Advocates, No. 30 at p. 2) DOE surmises that the Joint Advocates' uncertainty stems from the use of the acronym ''CHP'' in this sentence. DOE clarifies that ''CHP'' stands for ''central heat pump,'' not ''cold climate heat pump,'' and that the cut-out and cut-in temperature verification test in appendix J of the respective AHRI Drafts applies to all central heat pumps.

2. Controls Verification Procedure

(a) DOE's Proposal

In the April 2024 NOPR, DOE proposed to establish requirements for DOE's use of the CVP per appendix I of AHRI 210/240–202X Draft and AHRI 1600–202X Draft for the purposes of assessment and enforcement testing. 89 FR 24206, 24243–24244.

DOE proposed that if after conducting the CVP 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 [54] (10 percent) for the applicable CVP load 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. 89 FR 24206, 24244. DOE clarified that these tests will be conducted based on the override instructions from the manufacturer for setting the appropriate compressor and fan speeds for each test. *Id.*

However, if either of the full- or minimum-load CVP intervals fail to meet the required tolerances, and the control device allows monitoring and adjustment of the compressor and indoor blower speeds, and is the same control device used for certification and CVP tests,[55] DOE proposed that it will conduct certification tests by setting the speeds for the tests to the average values observed during the corresponding failed CVP interval.[56] 89 FR 24206, 24244. Alternatively, 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 or is not the same control device used for certification tests, DOE proposed to use the 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 EER, for appendix M2. *Id.* For certification tests that do not have a corresponding CVP interval, DOE proposed to calculate the corresponding efficiency by adjusting the capacity and power, by application of a ratio to the corresponding CVP interval.[57] *Id.*

For CHPs determined to be a 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 proposed to 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 $H1_{Nom}$, $H2_{Full}$, $H2_{Low}$, and $H3_{Low}$, as applicable, using the certified instructions, and for other certification tests, calculate the corresponding efficiency by adjusting the capacity and efficiency, by application of a ratio to the corresponding CVP interval.[58] 89 FR 24206, 24244. Otherwise, DOE proposed that 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 (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). *Id.*

(b) Comments Received

In response to these proposals, DOE received several comments related to various aspects of the CVP's adoption for enforcement and assessment testing. The comments are summarized in the following subsections.

(1) General Feedback

Lennox, the CA IOUs, Rheem, and GE Appliances all supported DOE's proposed CVP enforcement provisions utilizing the methods in the AHRI 210/240 and AHRI 1600 standards. (Lennox, No. 24 at p. 5; CA IOUs, No. 32 at p. 2; Rheem, No. 34 at p. 5; GE Appliances, No. 37 at p. 4) The CA IOUs commented that the new provisions in AHRI 210/240 will help consumers realize that heat pumps are an efficient means for space heating and cooling. (CA IOUs, No. 32 at p. 2)

AHRI pointed out the differences between the CVP outlined in AHRI 210/

[53] *See* 89 FR 24206, 24243.

[54] EER2 and COP2 for cooling load intervals and heating load intervals, respectively, when tested in accordance with appendix M1, and EER and COP, for cooling load intervals and heating load intervals, respectively, when tested in accordance with appendix M2.

[55] 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.

[56] For tests that do not correspond to any load intervals of the CVP, DOE proposed to adjust the compressor speed as follows: the compressor speeds for tests B_{Full}, B_{Low}, $H_{3,low}$, and $H0_{Low}$ will be set at the same speeds observed in the CVP load intervals associated with the A_{Full}, F_{Low}, $H3_{Full}$, $H4_{Full}$, and $H1_{Low}$ tests, respectively.

[57] As an example per the proposal, 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.

[58] As an example, the capacity at HO_{Low} condition, $Q_{H0,Low}$, will be calculated by the following equation: $Q_{H0,Low} = Q_{H0,Low,Certification} \times Q_{CVP,H1,Low}/Q_{H1,Low,Certification}$.

240 and AHRI 1600, and the CVP outlined in the ENERGY STAR® Version 6.1 (''EPA Energy Star CVP'')

Specifications for CACs and Air-Source Heat Pumps (''ASHPs''),[59] which are shown in table III.1. (AHRI, No. 25 at pp. 8–9)

TABLE III—1 SUMMARY OF CVP IN AHRI 210/240 AND THE EPA ENERGY STAR CVP

[AHRI, No. 25 at pp. 8–9]

Test type	Test segments CAC	Test segments CHP	Test duration for CAC	Test duration for CHP
AHRI 210/240 and AHRI 1600—Appendix I	3	6	9–19 hours	18–38 hours.
EPA Energy Star CVP	None	1	None	Up to 2 hours.

Similarly, LG commented that even though the Energy Star CVP is used to certify ENERGY STAR CCHPs, DOE's Cold Climate Heat Pump Technology Challenge (''DOE CCHP Tech Challenge'')[60] implemented a ''Min/Mild'' CVP test.[61] (LG, No. 38 at p. 3) LG suggested that the presence of multiple CVPs to certify identical products would place undue test burden on manufacturers, and DOE should incorporate the ''Min/Mild'' CVP in their CVP enforcement provisions, rather than going with the CVP outlined in the AHRI 210/240 and 1600 standards. (*Id.*)

In response to AHRI's comment, DOE notes that the scope of the ENERGY STAR CVP only includes ENERGY STAR CCHPs, specifically performance at the 5 °F test condition. In contrast, the CVP outlined in AHRI 210/240–202X Draft and AHRI 1600–202X Draft is applicable more broadly to all variable-capacity CAC/HPs. Because of the increased scope of the latter CVP, more heating test conditions are included, resulting in increased heating tests, both in number and duration. The CVP outlined in appendix I of AHRI 210/240–202X Draft and AHRI 1600–202X Draft also includes a 5 °F test for all CHPs that report performance at the H4 conditions, and is functionally the same test as the ENERGY STAR CVP.

In response to LG, DOE notes that although the ''Min/Mild'' CVP is a load-based method, it has a different method of inducing the conditioning load on the indoor psychrometric chamber as opposed to the CVP outlined in AHRI 210/240–202X Draft and AHRI 1600–202X Draft. As DOE detailed in the January 2023 RFI, the ''Min/Mild'' CVP uses the test chamber-induced load application scheme, where a fixed cooling or heating load is applied to the psychrometric chamber, and the unit under test responds to the test chamber-induced load to maintain the desired set point temperature. 88 FR 4091, 4094–4095. In contrast, the CVP in AHRI 210/240–202X Draft and AHRI 1600–202X Draft uses the virtual load approach, where the load is varied to simulate the building response if the capacity of the unit under test does not match the imposed load. *Id.* DOE notes that the CVP outlined in appendix I of AHRI 210/240–202X Draft and AHRI 1600–202X Draft represents industry consensus to ensure that fixed-speed settings of variable-speed systems would be achieved using native (unfixed) control. 89 FR 24206, 24222. Therefore, DOE considers that the CVP in appendix I of AHRI 210/240–202X Draft and AHRI 1600–202X Draft is the most suitable option to support enforcement associated with testing conducted in accordance with appendices M1 and M2.

(2) Delaying CVP Compliance Due to Uncertain CVP Tolerances

As noted in section III.E.1 of this document, DOE proposed in the April 2024 NOPR that systems determined to be variable-capacity compressor systems; variable-capacity certified, single-capacity systems; or variable-capacity certified, two-capacity systems after conducting the CVP, must meet tolerances of 6 percent and 10 percent on capacity and energy efficiency, respectively. 89 FR 24206, 24244.

Lennox commented that the proposed tolerances appeared to be reasonable from Lennox's testing, but it noted that DOE should ensure that the proposed tolerances are not very stringent and expressed its openness to talk with DOE on the matter. (Lennox, No. 24 at p. 5) The Joint Advocates also supported the proposed tolerance values and requested that DOE continue evaluating appropriate values for the tolerances. (Joint Advocates, No. 30 at p. 1).

AHRI, Carrier, Daikin, GE Appliances, JCI, LG, and Rheem had several issues with the aforementioned tolerances on capacity and energy efficiency for the CVP enforcement proposed by DOE, and they requested that DOE delay the compliance date CVP enforcement testing. (AHRI, No. 25 at p. 8; Carrier, No. 29 at p. 2; Daikin, No. 36 at pp. 3–4; GE Appliances, No. 37 at p. 4; JCI, No. 35 at pp. 2–3; LG, No. 38 at p. 1; Rheem, No. 34 at p. 5)

AHRI commented that even though the tolerances proposed by DOE were discussed with all stakeholders during development of the AHRI 210/240 and AHRI 1600 standards, AHRI is aiming to conduct CVP testing during 2025, analyze the proposed tolerances, and provide the relevant information to DOE by spring 2026, which will determine if the proposed tolerances are supported by test data. (AHRI, No. 25 at p. 8) Therefore, AHRI requested that DOE defer the effective date of CVP enforcement provisions to July 2026 at the earliest. (*Id.* at p. 9)

Carrier recommended that DOE delay the compliance date of the CVP enforcement to be 360 days after the publication of the final rule and revisit the proposed tolerances on capacity and efficiency once the industry has test data available to confirm appropriate tolerance values. (Carrier, No. 29 at p. 2) Carrier further commented that even though the tolerances proposed by DOE were discussed with stakeholders during the Unitary Small Equipment Standards Technical Committee (''USE STC'') negotiations, the consensus was

[59] *See: www.energystar.gov/sites/default/files/asset/document/ENERGY%20STAR%20Version%206.1%20Central%20Air%20Conditioner%20and%20Heat%20Pump%20Final%20Specification%20%28Rev.%20January%20%202022%29.pdf.*

[60] 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 *https://www.energy.gov/eere/buildings/cchp-technology-challenge-specifications.*

[61] The ''Min/Mild'' test is a load-based test conducted at outdoor conditions of 47 °F dry bulb temperature, and 43 °F wet bulb temperature, and indoor conditions of 70 °F dry bulb temperature and 60 °F wet bulb temperature, in order to validate the minimum capacity (at 47 °F outdoor dry bulb temperature) of CCHPs participating in the DOE CCHP Tech Challenge.

to not specify any tolerances at that time due to a lack of lab test data and uncertainty in the CVP. (*Id.*) Carrier expressed concern that the proposed tolerances would result in inappropriate characterization of system performance and may require manufacturers to retest and recertify products, thereby increasing the cost of testing. (*Id.*)

Daikin commented that it does not have sufficient test data from Daikin's own test laboratories to agree or disagree with the tolerances proposed by DOE. (Daikin, No. 36 at pp. 3–4) Daikin requested that DOE be open to delay CVP enforcement dates and changes to the tolerances once stakeholders can provide test data to either validate or modify the current tolerances. (*Id.*)

GE Appliances commented that it agrees with AHRI's recommendation on delaying CVP enforcement to no sooner than July 2026. (GE Appliances, No. 37 at p. 4) GE Appliances further commented that this will allow time for lab testing to validate DOE's proposed tolerances, and for building additional lab capacity for CVP testing, which takes longer than some existing CVP procedures, such as the ENERGY STAR CVP. (*Id.* at pp. 4–5) GE Appliances expressed concern that there are some items [62] in the CVP in AHRI 210/240 that may require changes to the tolerances proposed by DOE. (*Id.*) GE Appliances pointed to a mismatch between the text and the equations in 10 CFR 429.134(k)(4)(iii)(B), stating that the language regarding capacity and efficiency tolerances provide for a two-sided tolerance, while the formulas only allow for one side of the range. (*Id.* at p. 5) GE Appliances recommended that the capacity equations should be modified to show a two-sided tolerance (ensuring consistency with the text), but since a one-sided tolerance seems appropriate for efficiency, the text in 429.134(k)(4)(iii)(D) should be updated to note that the equations are not ''within'' the specified tolerance and are one sided. (*Id.*)

JCI commented that since the CVP tests proposed in AHRI 210/240 are complex and time consuming, it is crucial for laboratories under the AHRI audit program to put in place tolerances that are achievable. (JCI, No. 35 at p. 3) JCI requested that DOE delay CVP enforcement testing until sufficient CVP test data has been collected by labs to establish such tolerances. (*Id.*)

LG commented that since the CVP is a new and untried procedure, the capacity and efficiency tolerances proposed by DOE, of 6 percent and 10 percent respectively, should be reevaluated before finalizing the CVP enforcement. (LG, No. 38 at p. 1) LG asserted that the proposed tolerances may not be sufficient to compare a certification test with the CVP test, noting that the certification tests utilize fixed compressor speed and airflow rate while the CVP tests modulate compressor speed and airflow rate to optimize thermal comfort and system performance. (*Id.*) Additionally, LG commented that even though the CVP would only be utilized during enforcement testing, manufacturers would need to verify CVP test values in order to internally assess the products, for which third-party testing may also be required to obtain reliable test data. (*Id.* at p. 3) LG asserted that while self-verification in the manufacturer's internal lab may be available, this option also requires additional testing time and cost. (*Id.*) Therefore, LG requested that DOE align the compliance date of the CVP enforcement with appendix M2's effective date, since manufacturers will have to do some retesting and recertification with the advent of appendix M2, and this would help reduce their overall test burden. (*Id.*)

Similarly, Rheem questioned if there was adequate test data available to justify the tolerances on capacity and energy efficiency proposed by DOE for the full- and minimum-load intervals. (Rheem, No. 34 at p. 5) Rheem requested delaying the compliance data of the CVP to July 2026 so that the CVP test data collected by AHRI in 2025 may be analyzed and help validate the proposed tolerances. (*Id.*) Rheem referred to a residential furnace fans final rule published by DOE in the **Federal Register** on July 3, 2014 (''July 2014 Furnace Fan Final Rule''), in which the fan energy rating (''FER'') metric's enforcement was delayed by DOE. (*Id.* at p. 6) Rheem commented that DOE should utilize the aforementioned flexibility in delaying enforcement provisions, in order to delay enforcement of the CVP. (*Id.*) Rheem noted that section I5.1.5 from appendix I of AHRI 210/240–2024 and AHRI 1600–2024—which prescribes a maximum allowable variation in EER/COP equal to 5 percent—is redundant, given that all condition and operating tolerances have already been prescribed in section I5 and in the CVP enforcement provisions by DOE at 10 CFR 429.134(k). (*Id.* at p. 7)

As noted by AHRI, the CVP tolerances on capacity and efficiency, 6 percent and 10 percent, respectively, were discussed with the stakeholders during the development of the AHRI standards. During these discussions, DOE presented unit capacity, compressor speed, and efficiency data on 10 different variable-speed CHPs—five (5) ducted split CHPs and five (5) ductless mini-split CHPs. The CHP units were from seven (7) different manufacturers and had capacities ranging from 1.5 tons to 3 tons. Regulatory cooling and heating tests were conducted on these units as per the existing appendix M1 procedure, and CVP tests were conducted using the test chamber-induced load application scheme, as explained in section III.I.2.b.(1) of this document. The SEER2 and HSPF2 metrics were evaluated for the units using both the regulatory test values and those obtained from the CVP. Table III–2 shows the comparison of the regulatory and CVP capacities and energy efficiency for each of the 10 units, for cooling full load, cooling low load, heating full load, and heating low load. The following can be observed, if 10% is the allowable tolerance for capacity and efficiency, when comparing the regulatory and CVP values: (1) unit 1 was out of tolerance on the cooling full load, and heating low load capacity and efficiency, (2) unit 3 was out of tolerance on the cooling low load capacity, and heating low load capacity and efficiency, (3) unit 6 was out of tolerance on the heating full load and heating low load capacity and efficiency, (4) unit 9 was out of tolerance on the cooling low load and heating low load efficiency, and (5) unit 10 was out of tolerance on the cooling low load and heating low load capacity and efficiency. For the aforementioned units, the SEER2 values were recalculated by use of the tested out of tolerance CVP load intervals and adjustment of the applicable load intervals without a CVP for full load or low load efficiencies and capacities, using the following equations:

[62] GE Appliances, in its example, pointed out that the target sensible load for the full-load and low-load tests were set at 97 percent and 103 percent respectively, which may lead to unbalanced bilateral tolerance.

$$\dot{q}_{B,Full} = \dot{q}_{B,Full,Certification} \times \frac{\dot{q}_{CVP,A,Full}}{\dot{q}_{A,Full,Certification}}$$

$$P_{B,Full} = P_{B,Full,Certification} \times \frac{P_{CVP,A,Full}}{P_{A,Full,Certification}}$$

$$\dot{q}_{B,Low} = \dot{q}_{B,Low,Certification} \times \frac{\dot{q}_{CVP,F,Low}}{\dot{q}_{F,Low,Certification}}$$

$$P_{B,Low} = P_{B,Low,Certification} \times \frac{P_{CVP,F,Low}}{P_{F,Low,Certification}}$$

TABLE III–2—REGULATORY AND CVP CAPACITY AND ENERGY EFFICIENCY OF 10 VARIABLE SPEED CHPS

Unit No.	Test	Certification capacity (Btu/hr)	CVP capacity (Btu/hr)	Certification efficiency *	CVP efficiency *	%age difference in capacity	%age difference in efficiency
1	Cooling Full	22,515	25,343	13.2	11.6	−13	12
	Cooling Low	6,521	6,870	23.6	22.5	2	5
	Heating Full	18,853	18,659	2.0	2.0	1	0
	Heating Low	10,138	15,309	4.4	3.8	27	14
2	Cooling Full	18,614	17,423	15.0	15.2	6	−2
	Cooling Low	11,444	12,325	17.6	15.8	5	10
	Heating Full	10,787	15,961	2.3	2.1	−48	11
	Heating Low	9,837	10,591	3.7	2.5	7	32
3	Cooling Full	33,062	32,397	12.7	12.7	2	0
	Cooling Low	16,969	23,183	19.1	18.2	19	5
	Heating Full	19,038	19,120	2.0	2.1	0	−3
	Heating Low	16,373	20,290	4.9	4.3	21	13
4	Cooling Full	34,439	33,290	13.0	12.7	3	3
	Cooling Low	13,196	13,660	24.2	24.5	1	−1
	Heating Full	18,707	25,224	2.1	1.9	−35	11
	Heating Low	9,880	10,081	4.1	4.1	1	1
5	Cooling Full	22,655	21,477	13.5	13.8	5	−2
	Cooling Low	6,373	7,031	24.0	23.3	3	3
	Heating Full	19,415	18,423	2.1	2.0	5	3
	Heating Low	10,092	10,011	4.5	3.8	0	16
6	Cooling Full	21,668	22,734	12.7	12.1	−5	5
	Cooling Low	11,124	11,018	20.8	18.8	0	9
	Heating Full	12,992	22,441	2.6	1.9	−73	26
	Heating Low	9,197	10,934	5.2	4.5	13	13
7	Cooling Full	33,470	33,290	12.7	12.7	1	0
	Cooling Low	12,503	13,660	23.9	24.5	3	−2
	Heating Full	17,430	17,217	2.0	2.0	1	−1
	Heating Low	9,871	9,915	4.4	4.3	0	2
8	Cooling Full	35,324	38,800	13.7	13.4	−10	3
	Cooling Low	20,254	20,824	19.9	19.1	2	4
	Heating Full	37,690	37,498	2.4	2.4	1	0
	Heating Low	20,128	19,479	4.5	4.4	−2	2
9	Cooling Full	22,515	22,455	13.2	13.4	0	−2
	Cooling Low	6,521	6,602	23.6	18.3	0	22
	Heating Full	18,853	18,890	2.0	2.0	0	1
	Heating Low	10,138	10,199	4.4	3.9	0	12
10	Cooling Full	15215	14969	14.1	13.3	2	6
	Cooling Low	4,752	5,497	30.3	27.3	5	10
	Heating Full	20,509	18,824	2.2	2.1	8	6
	Heating Low	3,644	4,998	6.1	5.1	7	17

* EER2 for cooling tests (in Btu/hr/W), COP2 for heating tests.

The recalculated SEER2 for units 1, 3, 6, 9 and 10, are shown in table III–3, indicating that the highest difference between the recalculated (or adjusted) SEER2 was no greater than 9.7%. Unit 6 was in tolerance for both the full and low load intervals and the reduction in SEER2 using the adjusted values was 6.3%. Therefore, it was concluded that a maximum energy efficiency tolerance of 10% would be appropriate for CVP enforcement of variable capacity compressor systems.

TABLE III–3—COMPARISON OF RECALCULATED SEER2 WITH THE CERTIFIED SEER2 FOR UNITS THAT WERE OUT OF TOLERANCE ON CAPACITY AND/OR EFFICIENCY

Unit No.	Certified SEER2	Adjusted SEER2	%age difference between adjusted and certified SEER2
1	17.50	16.66	−4.9
3	17.02	16.22	−4.7
6	18.88	17.69	−6.3
9	17.51	15.81	−9.7
10	23.84	22.64	−5.0

For capacity, the tolerance of 6% was proposed in the April 2024 NOPR, as a result of discussions with stakeholders during development of appendix I of the AHRI 210/240–202X Draft and AHRI 1600–202X Draft. 89 FR 24206, 24243–24244. In appendix I of the AHRI 210/240–202X Draft and AHRI 1600–202X Draft, equations I2 and I3 show the calculation of the cooling virtual sensible load at outdoor conditions of 95 °F and 67 °F, respectively, and equations I9, I10, and I11 show the calculation of the heating virtual load at outdoor conditions of 5 °F, 17 °F, and 47 °F, respectively. Each of these equations provide a 3% factor on the cooling and heating full load and low load target virtual loads. Based on the data presented above in table III–2 and the discussions with relevant stakeholders during the development of appendix I of the AHRI 210/240–202X Draft, DOE has determined 6% as an appropriate tolerance for capacity measurements during the CVP test.

During development of the AHRI Standards, no counter data was presented by any of the stakeholders to suggest revising the tolerances of 6% on unit capacity, and 10% on unit efficiency, for CVP enforcement. DOE has also not received any CVP test data in response to the April 2024 NOPR to indicate that the proposed tolerances are not appropriate. Therefore, DOE is finalizing the aforementioned tolerances as part of the CVP enforcement provisions at 10 CFR 429.134(k).

Regarding delaying the CVP enforcement date so that stakeholders have sufficient time to conduct CVP testing and for DOE to wait for AHRI's CVP testing in 2025 to help inform the proposed capacity and efficiency tolerances, DOE notes that the CVP is not required as part of testing, and a manufacturer is currently required to certify the compressor and indoor blower speed at settings that represent normal operation for any variable capacity system. Therefore, some form of validation to determine the settings for normal operation should already be in place to allow the manufacturers to properly certify these settings. The CVP outlined in appendix I of AHRI 210/240–202X Draft and AHRI 1600–202X Draft is intended to standardize such a procedure. Hence, even if manufacturers wanted to prepare to conduct the CVP on their products to prepare for potential enforcement by DOE, the test burden is limited.

Regarding Rheem's comment on DOE delaying the enforcement of the FER metric for furnace fans, DOE clarifies that the FER metric was established as a regulatory metric, and is hence not comparable to the CVP procedure in appendix I of AHRI 210/240–202X Draft and AHRI 1600–202X Draft, which DOE intends to utilize only for the purposes of assessment and enforcement testing of variable-capacity compressor systems. As discussed, the enforcement provisions explain what DOE may do in the case of enforcement testing for CAC/HPs and are not a requirement for manufacturer testing. As such, DOE does not see reason to delay the CVP enforcement provisions from their current effective date, *i.e.,* 180 days after publication of this final rule in the **Federal Register**.

DOE considers that the proposed tolerances on capacity and energy efficiency, of 6 percent and 10 percent, respectively, are currently the most appropriate values based on the variable-speed test data analyzed by DOE. At this time, no additional data is available nor has been provided by stakeholders and, therefore, DOE is finalizing its proposals on the tolerances and is not establishing a delayed effective date for the CVP. DOE welcomes any additional CVP test data as it becomes available.

DOE agrees with GE Appliances' comment on the mismatch between the text and the equations in 10 CFR 429.134(k)(4)(iii)(B). (GE Appliances, No. 37 at p. 5) DOE`s intent was to maintain a one-sided tolerance on capacity and efficiency since the unit under enforcement should not be penalized for better performance during the CVP load interval, when compared to the corresponding certification test. Therefore, DOE is maintaining the equations on capacity tolerance evaluation, but it is making corrections to the text in 10 CFR 429.134(k)(4)(iii)(B) and 10 CFR 429.134(k)(4)(iii)(C) as follows (additions shown in *italics*, deletions shown in ~~strikethrough~~):

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 percent~~ *be no more than 6 percent less than the corresponding certification test capacity*, as follows:

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~~

In response to Rheem's comment (Rheem, No. 34 at p. 5) regarding the tolerances specified in section I5 in appendix I of AHRI 210/240–202X Draft and AHRI 1600–202X Draft being redundant, DOE clarifies that this tolerance was incorporated in order to determine if the variable-capacity compressor system under test met the stability requirements and subsequently determines the appropriate CVP test interval to be evaluated. Therefore, DOE disagrees with Rheem that this tolerance is redundant in the AHRI drafts.

~~with the corresponding certification test within 6 percent of the cooling or heating mode full-load certification test capacity~~ *be no more than 6 percent less than the corresponding certification test capacity*, as follows:

Similarly, DOE agrees with GE Appliances that a one-sided tolerance on efficiency will be appropriate. Therefore, DOE is maintaining the equations on efficiency tolerance evaluation, but it is making corrections to the text in 10 CFR 429.134(k)(4)(iii)(D), as follows (additions shown in *italics*, deletions shown in ~~strikethrough~~):

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 percent~~ *be no more than 10 percent less than the corresponding certification test efficiency*, as follows:

(3) Clarification on Enforcement Provisions

Several commenters requested more clarity on the CVP enforcement provisions and made their own recommendations for some of the calculations and provisions proposed by DOE.

The Joint Advocates pointed to DOE's proposal for evaluation of CVP results when tolerances on capacity and energy efficiency are not met, and the control used for conducting CVP does not provide means for overriding compressor and indoor blower speeds (10 CFR 429.134(k)(4)(v)(B)) to adjust power measurements. (Joint Advocates, No. 30 at p. 2) In this case, the Joint Advocates commented that DOE proposed that power adjustment should be done by multiplication with the ratio of the efficiency measured during the CVP test interval divided by efficiency measured during the certification test (for the corresponding CVP interval). (*Id.*) The Joint Advocates noted that because of the 6-percent tolerance allowed for the full-load CVP interval-capacity measurements, the capacity ratio may not be equal to 1, and hence it may not be appropriate to use the ratio of efficiencies (EER2 or COP2, as applicable). (*Id.*) The Joint Advocates suggested that DOE consider adjusting power by multiplying the ratio of powers, as follows:

$$P_{B,Full,} = P_{B,Full,Certification} \times \frac{P_{CVP,A,Full}}{P_{A,Full,Certification}}$$

Additionally, the Joint Advocates pointed to the provisions in 10 CFR 429.134(k)(4)(v)(A) and (B)—where DOE proposed that for CVP tests for which capacity and efficiency tolerances are not met, the certification tests must be conducted by using the compressor speeds determined in the corresponding CVP test (or certification test results must be adjusted) and the certification tests will be used for calculating the unit's efficiency metrics. (*Id.* at p. 3) The Joint Advocates expressed concern that if the recalculated efficiency metric is compliant, but is lower than the value certified to DOE, this will result in a misleading efficiency rating and average energy cost printed on the FTC label. (*Id.*) The Joint Advocates pointed toward the rerate and recertify provision [63] for VRF multi-split air conditioners and heat pumps (''VRF

[63] In the October 2022 VRF Final Rule, DOE specifies that if a manufacturer becomes aware that any of the certified operational settings for the critical parameters are determined to be invalid according to the results of a CVP, whether that CVP be performed by the manufacturer or another party, the manufacturer would be required to recertify the operational settings of those critical parameters for all affected basic models, as well as rerate and recertify the affected basic models.

multi-split systems''), which was specified by DOE in a final rule on October 20, 2022, suggesting that a similar provision should be adopted for CAC/HPs (''October 2022 VRF Final Rule''). 87 FR 63894.

In response to the Joint Advocates' comment on adjustment of power of certification tests for which a corresponding CVP interval did not exist, DOE did an analysis on an example case for a variable-capacity CAC unit. DOE assumed that for a hypothetical variable-capacity compressor 3-ton CAC unit, with a certified $EER2_{A,Full}$ of 12, the capacity at B_{Full} condition was 40,000 Btu/hr, and the $EER2_{B,Full}$ was 15. It was assumed that after conducting the CVP on the unit, the value of the EER2 measured using the full-load CVP test dropped to 11.28, as shown in table III.4. DOE then evaluated the capacity and power at the B_{Full} condition—the power was adjusted by using the energy efficiency ratios first, as proposed by DOE in the April 2022 CAC NOPR, and was separately adjusted by using the power ratios, as suggested by the Joint Advocates.

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Table III-4 Evaluating the Capacity and Power Measurement Adjustments for Certifications Tests with No CVP Interval, in the Event that CVP Tolerances Are Not Met

Certification test values			
$\dot{q}_{A,Full,Certification}$	36,000 Btu/h		
$P_{A,Full,Certification}$	3,000 W		
$EER2_{A,Full,Certification}$	12.0 Btu/Wh		
$\dot{q}_{B,Full,Certification}$	40,000 Btu/h		
$P_{B,Full,Certification}$	2,667 W		
$EER2_{B,Full,Certification}$	15.0 Btu/Wh		
CVP test values			
$\dot{q}_{CVP,A,Full}$	33,840 Btu/h		
$P_{CVP,A,Full}$	3,000 W		
$EER2_{CVP,A,Full}$	11.28 Btu/Wh		
Adjustments of power and energy efficiency using energy efficiency ratios			
$\dot{q}_{B,Full} = \dot{q}_{B,Full,Certification} \times \frac{\dot{q}_{CVP,A,Full}}{\dot{q}_{A,Full,Certification}}$	3,7600 Btu/hr	$\frac{\dot{q}_{B,Full} - \dot{q}_{B,Full,Certification}}{\dot{q}_{B,Full,Certification}} \times 100$	-6.0%
$P_{B,Full} = P_{B,Full,Certification} \times \frac{EER2_{CVP,A,Full}}{EER2_{A,Full,Certification}}$	2,837 W	$\frac{P_{B,Full} - P_{B,Full,Certification}}{P_{B,Full,Certification}} \times 100$	-6.4%
$EER2_{B,Full} = \frac{\dot{q}_{B,Full}}{P_{B,Full}}$	13.25	$\frac{EER2_{B,Full} - EER2_{B,Full,Certification}}{EER2_{B,Full,Certification}} \times 100$	-11.6%
Adjustments of power and energy efficiency using power ratios			
$\dot{q}_{B,Full} = \dot{q}_{B,Full,Certification} \times \frac{\dot{q}_{CVP,A,Full}}{\dot{q}_{A,Full,Certification}}$	3,7600 Btu/hr	$\frac{\dot{q}_{B,Full} - \dot{q}_{B,Full,Certification}}{\dot{q}_{B,Full,Certification}} \times 100$	-6.0%
$P_{B,Full} = P_{B,Full,Certification} \times \frac{P_{CVP,A,Full}}{P_{A,Full,Certification}}$	2,667 W	$\frac{P_{B,Full} - P_{B,Full,Certification}}{P_{B,Full,Certification}} \times 100$	0.0%
$EER2_{B,Full} = \frac{\dot{q}_{B,Full}}{P_{B,Full}}$	14.10 W	$\frac{EER2_{B,Full} - EER2_{B,Full,Certification}}{EER2_{B,Full,Certification}} \times 100$	-6.0%

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DOE observed that adjusting the power using the energy efficiency ratios resulted in the certification and CVP values for energy efficiency being out of tolerance, *i.e.,* −11.6 percent, whereas adjusting the power using the power ratios resulted in this difference being −6 percent. Additionally, DOE revisited its analysis of the regulatory and CVP test data of the 10 variable-speed CHPs that was used to develop the 6-percent tolerance on capacity and 10-percent tolerance on efficiency, as explained in section III.I.2.b.(2) of this document. DOE observed that for one of the units, the power ratio adjusted $EER2_{B,Low}$ value was only 5.9 percent lower than the actual EER2 for the B_{low} CVP test, , but the efficiency ratio adjusted $EER2_{B,Low}$ was 26 percent higher than

the . DOE realizes that using the efficiency ratios to adjust power measurements may result in inflated energy efficiencies of the variable-capacity compressor units that DOE will run a CVP on. Therefore, DOE is adopting the proposed revision by the Joint Advocates and modifying the equations at 10 CFR 429.134(k)(4)(v)(B) that are used to adjust the power measurements for certification tests requiring adjustment with no CVP interval (any required certification test other than A_{Full}, F_{Low}, $H1_{Low}$, $H3_{Full}$, and $H4_{Full}$), as follows:

Cooling full power:

$$P_{B,Full} = P_{B,Full,Certification} \times \frac{P_{CVP,A,Full}}{P_{A,Full,Certification}}$$

Cooling minimum power:

$$P_{B,Low} = P_{B,Low,Certification} \times \frac{P_{CVP,F,Low}}{P_{F,Low,Certification}}$$

Heating minimum power:

$$P_{H0,Low} = P_{H0,Low,Certification} \times \frac{P_{CVP,H1,Low}}{P_{H1,Low,Certification}}$$

Regarding the Joint Advocates' recommendation to establish a rerate and recertify provision similar to the one in the October 2022 VRF Final Rule (*see* § 429.43(b)(5)), DOE notes that if a variable-capacity compressor system meets the minimum standards after the CVP assessment or enforcement, but the recalculated metric is lower than the value certified to DOE, DOE may choose to take enforcement action regarding invalid certification of the basic model. At this time, DOE is not adopting the rerate and recertify provision but may consider inclusion in a future certification rulemaking.

In response to the CVP enforcement provisions, Rheem requested several clarifications and made its own recommendations, including some changes and corrections to the finalized standards, AHRI 210/240–2024 and AHRI 1600–2024.

Rheem requested clarification from DOE on the provisions in 10 CFR 429.134(k)(4)(iii)(B) and (D). 89 FR 24206, 24259. (Rheem, No. 34 at p. 6) Rheem noted that at 10 CFR 429.134(k)(4)(iii)(B) and (D), DOE proposed maximum allowable tolerances between the heating capacity and heating efficiency measured during the full-load interval of the CVP and the corresponding certification test. (*Id.*) Rheem commented that the proposed regulatory text in the section reads as if the full-load interval of the heating mode CVP must be conducted at both 17 °F and 5 °F, while section I4.2.1 of AHRI 210/240–2024 and AHRI 1600–2024 does not require full-load interval of the heating CVP to be conducted at both 17 °F and 5 °F for all heat pumps. (*Id.*) Additionally, Rheem noted that in 10 CFR 429.134(k)(4)(i)(C), DOE proposed that the CVP will be allowed to be terminated without conducting the minimum load interval if, according to 10 CFR 429.134(k) (4)(ii)(B), a system is determined to be a variable-capacity certified, single-capacity system. 89 FR 24206, 24258. (Rheem, No. 34 at p. 6) Rheem commented that it interprets this provision to mean that in such a case, capacity, and energy efficiency tolerance at low-load intervals, as per 10 CFR 429.134(k)(4)(iii)(C) and (D), will not be necessary. (*Id.*) In 10 CFR 429.134(k)(v)(B), Rheem noted that DOE proposed to use the capacity slope factor (''CSF'') and power slope factor (''PSF'') for extrapolating an ''adjusted'' heating capacity and heating power consumption at H3 (17 °F outdoor dry bulb temperature) test condition when the compressor is operating at low stage, using the system's measured performance during the heating mode CVP's low-load interval. (*Id.*) 89 FR 24206, 24260–24261. Rheem commented that the values of CSF and PSF will be adopted from AHRI 210/240–2024 or from section 3.6.4.1(b) of the current appendix M1, and it questioned their accuracy for low-speed compressor operation, since they were derived for compressor operation at full speed. (Rheem, No. 34 at p. 6) In its comment, Rheem also questioned the extrapolation using these CSF and PSF values for minimum-speed-limiting heat pumps, as defined [64] in AHRI 210/240–2024 and AHRI 1600–2024. (*Id.*) Finally, Rheem pointed to a typographical error in sections I4.3.1.4 of AHRI 210/240–2024 and AHRI 1600–2024, and it made suggestions for correcting it.[65] (*Id.*) Rheem commented that since no indoor entering wet bulb temperature is prescribed for any of the load and transition intervals of the heating CVP, corrections should be made in section I5.1 and section I5.1.3 of AHRI 210/240–2024 and AHRI 1600–2024 to reflect that any tolerances on indoor entering wet bulb temperatures should only be applicable to the cooling mode CVP tests. (*Id.* at p. 7)

In response to Rheem's comments, DOE clarifies that since the CVP for enforcement will be carried out as per appendix I of the AHRI 210/240 and AHRI 1600 standards, the full-load interval of the heating mode CVP at 5 °F will only be enforced for those CHPs that have reported regulatory

[64] Minimum-speed-limiting variable-speed HPs are defined at section 3.2.32 of AHRI 210/240–202X Draft and 3.2.31 of AHRI 1600–202X Draft as: A *heat pump* for which the minimum compressor speed (represented by revolutions per minute or motor power input frequency) is higher than its minimum value for operation in a 47 °F ambient temperature for any bin temperature *tj* for which the calculated heating load is less than the calculated intermediate-speed capacity.

[65] Rheem suggested that either the phrase ''. . . where the range of capacity does not vary by more than 15 percent'' should be deleted fully, or the words ''. . . does not vary'' should be replaced with the word ''varies,'' since the AHRI USE STC's intent when developing this requirement was to encapsulate systems that cycle on/off, instead of modulating between compressor speeds/stages.

performance at the $H4_{full}$ test, while the CVP at 17 °F will be carried out for all CHPs, including units for which performance at $H4_{full}$ conditions has not been reported. Additionally, DOE clarifies that for systems that are determined to be variable-capacity certified, single-capacity systems, as per 10 CFR 429.134(k) (4)(ii)(B), there will be no need to conduct the minimum load interval, and therefore, Rheem's understanding that capacity and energy efficiency tolerance at low load intervals, as per 10 CFR 429.134(k)(4)(iii)(C) and (D), will not be applicable, is correct. Regarding Rheem's comment on the use of CSF and PSF values from the AHRI standards, DOE notes that it has not received any test data from stakeholders that would indicate that the use of these slope factors is inaccurate at low compressor speed tests. In the absence of any test data, DOE is maintaining the CSF values of 0.0204/°F for split systems and 0.0262/°F for single-package units, and PSF value of 0.00455/°F, as per the April 2024 NOPR, to extrapolate an adjusted heating capacity and heating power consumption at H3 (17 °F) test conditions when the compressor is operating at low stage, using tested system performance during the heating CVP's low load interval. The CSF and PSF values are used for extrapolation at the $H3_{Low}$ test condition capacity and heating power consumption only for Variable Capacity Certified, Two Capacity Systems, when the control device for conducting the CVP and certification tests does not meet the requirements of monitoring and adjustment of the compressor speed and indoor blower speed, as outlined in 10 CFR 429.134 (k)(4)(v)(A).

In response to Rheem's comment on questioning this extrapolation for minimum-speed-limiting heat pumps, no evidence has been provided by Rheem to argue that the current CSF and PSF values may be inexact for the aforementioned extrapolation. However, DOE recognizes the concern raised by Rheem, and notes that systems determined to be Variable Capacity Certified, Two Capacity Systems, after conducting the CVP, will not be subject to extrapolation using the minimum speed limiting heat pump adjustments, as per equations 11.189 to 11.194 of AHRI 210/240–2024 when tested in accordance with appendix M1, and per equations 11.199 to 11.204 of AHRI 1600–2024, when tested in accordance with appendix M2. Additionally, DOE clarifies that there are no typographical errors in sections I4.3.1.4 of AHRI 210/240 and AHRI 1600—the phrase ''. . . where the range of capacity does not vary by more than 15 percent'' is referring to the range of capacity the unit can modulate from its high-/on-capacity value and is therefore consistent with the intent of this section. Regarding Rheem's comment on tolerances on indoor entering wet bulb temperature and indoor leaving wet bulb temperature (in sections I5.1 and I5.1.3, respectively) in AHRI 210/240 and AHRI 1600, being applicable to cooling mode CVP tests only, DOE agrees, and it is making amendments at 10 CFR 429.134(k)(4)(iii)(A) as follows (additions shown in *italics*):

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 210/240–2024 (incorporated by reference, *see* § 429.4) (if testing in accordance with appendix M1); or of AHRI 1600–2024 (incorporated by reference, see § 429.4) (if testing in accordance with appendix M2), *with the exception that the indoor entering wet bulb deviation in section I5.1 and test operating tolerance in section I5.1.3 are applicable only for cooling mode CVP.*

JCI also requested clarity on various aspects of the CVP enforcement provisions. (JCI, No. 35 at pp. 2–3). In particular, JCI expressed concern about systems that utilize variable-capacity compressors rated as ''coil only'' systems and ''certified'' to DOE as variable-capacity systems, but which are rated and tested per two-speed test procedures.[66] (*Id.*) JCI asserted that its concern stems from the broad definition of variable-capacity systems in AHRI 210/240–2024.[67] (*Id.*) JCI commented that according to its interpretation, if such a system is certified to DOE as a multi- or variable-stage design but is tested to the coil-only two-stage test procedure, then the system is subject to CVP test requirements. (*Id.*)

In a similar vein, JCI requested clarification on whether such systems, classified as OUWNMs (since they are sold in commerce without matching indoor units), would be subject to rating and testing per the CVP requirements. (JCI, No. 35 at pp. 2–3) Finally, JCI requested for clarification on whether DOE-certified, two-stage systems that have discrete fixed capacities and airflow rates, but are equipped with variable-capacity compressors, will be subject to the CVP enforcement or not. (*Id.* at p. 3)

In response to JCI's comment regarding the variable-speed coil-only (''VSCO'') test provisions in the October 2022 CAC TP Final Rule, DOE clarifies that once the revised appendix M1 and the new appendix M2 are finalized, the VSCO test provisions for non-communicating and communicating systems in the current appendix M1 will be sunset. This is because these provisions are not part of the AHRI 210/240 and AHRI 1600 standards, which are the basis of the revised appendix M1, and new appendix M2, respectively. Therefore, all VSCO systems will be certified and tested as variable-capacity compressor systems, and DOE may conduct the CVP on such units, to see if they comply with the variable-speed definition. JCI's question regarding OUWNMs is unclear—however, DOE clarifies that the CVP is applicable to all variable-speed systems, and therefore, if such systems are certified as variable-speed systems, they will be subject to CVP enforcement. Finally, DOE clarifies that the CVP enforcement is applicable only to systems that are certified as variable-capacity compressor systems, as defined in section 3.2.80 of AHRI 210/240–2024 and AHRI 1600–2024. Therefore, any systems that are certified as two-capacity (or two-stage) systems, as defined in section 3.2.76 of AHRI 210/240–2024 and AHRI 1600–2024, will not be subject to CVP enforcement by DOE.

GE Appliances supported the addition of a CVP for enforcement testing of variable-speed systems, but it commented that a number of lingering issues require resolution before DOE utilizes the CVP for enforcement testing.

[66] In the October 2022 CAC Final Rule, DOE defined ''variable-speed communicating coil-only central air conditioner or heat pump'' and ''variable-speed non-communicating coil-only central air conditioner or heat pump.'' 87 FR 64550,64589. DOE's understanding is that JCI is referring to non-communicating variable-speed coil-only (''VSCO'') CAC/HPs in their comment, since the October 2022 CAC Final Rule established a two-stage test procedure for non-communicating VSCO CAC/HPs. 87 FR 6450, 64591–64597. Such systems will only be tested using an on-off control signal and will not have any tests at intermediate speeds. *Id.*

[67] AHRI 210/240–2024 section 3.2.81 defines Variable Capacity System (Variable Capacity Air-conditioner or Variable Capacity Heat Pump): an air-conditioner or heat pump that has either a) a variable capacity compressor, or b) a digital compressor, and that controls the system by monitoring system operation and automatically modulating the compressor output, indoor airflow, and other system parameters as required in order to maintain the indoor room temperature.

(GE Appliances, No. 37 at p. 4) GE Appliances also commented that additional test data is required for validation of some provisions proposed by DOE in the April 2024 NOPR. (*Id.*) GE Appliances commented that the AHRI 210/240 standard specifies that the CVP tests should be done either with a proprietary control or with a simulated thermostat control, but it requested that DOE clarify when a control is considered proprietary, since multiple types of control systems are available, including those with hybrid control capability.[68] (*Id.* at pp. 5–6)

In response to GE Appliances, DOE clarifies that the differences between a proprietary control and simulated (generic) thermostat were discussed in detail with the stakeholders during the development of the AHRI 210/240 and AHRI 1600 standards. It is DOE's understanding and intent for implementation of the CVP that the ''control'' is the device that senses temperature in the conditioned space, has a user interface that allows setting of a desired space temperature (the ''set point''), and provides a signal or communication to the CAC or HP system that initiates system operation and/or steps or level of operation to reduce the gap between the temperature and the set point. Accordingly, as per the example scenario presented by GE Appliances in their comment, an adapter[69] provided as part of the system or specified for installation that allows the basic model to connect with any generic (non-proprietary) thermostat is not the ''control.'' In the case in which such an adapter allows a generic thermostat to be installed in the conditioned space, the generic thermostat is the control, and the simulation of the generic thermostat (as described in section I3.1 of AHRI 210/240–2024 and AHRI 1600–2024) would be used. Only when the device measuring the space temperature and providing user input to adjust the set point is proprietary would installation of the proprietary device for the test be used. Any system having a ''hybrid'' control approach that could use either a generic or proprietary ''control'' would be tested using the generic approach.

[68] GE Appliances gave an example of hybrid control where an adaptor can be connected to a 24–V thermostat and variable-speed communicating equipment. For such control systems, the thermostat sends an on/off signal, and the adaptor then decides the set point temperature during unit operation.

[69] DOE would like to clarify that if the adapter is an integral part of every unit shipped without a proprietary control that would otherwise not operate, the adapter would be connected to the simulated thermostat signal.

LG also made several comments in response to the CVP enforcements proposed by DOE in the April 2024 NOPR. 89 FR 24206, 24258–24261. LG pointed out that as per the CVP, the indoor room's set point is controlled according to the virtual load approach, in which the range of temperature difference between the thermostat set point and the indoor room condition during the proposed CVP test is 0–3 °F. (LG, No. 38 at pp. 1–2) LG questioned whether the virtual load is appropriate for variable-capacity systems that do not operate at minimum speed when the indoor room temperature is not close to the thermostat set point. (*Id.*) LG further expressed concern that the term ''certification'' test was not fully specified, as it could mean either (1) the tested value of the certification test, or (2) the value of the enforcement test conducted under the same conditions as the certification test. (*Id.* at p. 2) LG commented that if the ''certification'' test was (1), it requests clarification if this would be a mean value of the two or more tested samples. (*Id.*) However, if it was (2), then LG requested that DOE provide more information on sample size and election.[70] (*Id.*) Finally, LG recommended that due to existing deviations during testing, instead of comparing the CVP test values with the certification test values during enforcement, they should be compared to values provided by the manufacturer in the DOE database.[71] (*Id.*)

In response to LG's comment, DOE clarifies that the return air temperature equation in appendix I of AHRI 210/240–2024 is a function of the previous return air temperature target, *RAT(t),*time, the calculated virtual load (VL_s for cooling mode CVP, and *VL* for heating mode CVP) at target outdoor ambient dry-bulb temperature T_j, measured unit capacity, and a thermal mass constant, *C.* The difference between the thermostat set-point and indoor room dry-bulb temperature is dependent on the unit control and operation. The virtual load and return air temperature equations ensure the temperature difference between the thermostat set-point and indoor room dry-bulb temperature are within 1 °F for systems that control the unit properly. The difference between the thermostat set-point and indoor room dry-bulb temperature could reach 3 °F only if the unit could not achieve the virtual load target capacity at each test interval.

[70] Currently, 10 CFR 429.16 (b)(3) describes the sampling plan for enforcement of CAC/HPs.

[71] DOE's interpretation is that LG is referring to the Compliance Certification Database, available at *www.regulations.doe.gov/ccms.*

Further, DOE clarifies that ''the corresponding certification test'' refers to an enforcement test conducted in accordance with appendix M1 or appendix M2, as applicable. The sample size of the selected units will be in accordance with provisions in 10 CFR 429.110. Finally, DOE clarifies that during the CVP enforcement, comparisons of the CVP full and minimum load intervals will be made to the certification test conducted just before the CVP tests.

Carrier requested clarity from DOE on determining variable-speed unit operation when the intermediate tests do not show satisfactory variable-speed characteristics. (Carrier, No. 29 at p. 2) Specifically, Carrier commented that it was unclear on whether DOE's proposal on a system's cycling between stages is an accurate way of determining it is a single-capacity versus a two-capacity system, if the intermediate CVP requirement is not met. (*Id.*)

In response to Carrier's comment, DOE clarifies that 10 CFR 429.134(k)(4)(C)(ii)(B) and (k)4)(C)(ii)(C) state that after conducting the CVP enforcement tests, the unit under test will be determined to be a variable-capacity certified, single-capacity system, or a variable-capacity certified, two-capacity system, on the basis of the test results as per appendix I of AHRI 210/240 and AHRI 1600 (*see* section III.E.1 of this document for details). DOE reiterates that this determination, on whether a system is single capacity or two capacity, on the basis of its cycling between off and single-stage/capacity level and cycling between more than one stage/capacity level, respectively, represents industry consensus on this matter. This is because this determination was discussed and agreed upon with AHRI and all other stakeholders, during development of appendix I of the AHRI 210/240 and AHRI 1600 standards.

J. Test Procedure Costs and Impacts

EPCA requires that test procedures proposed by DOE not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3)) As discussed, DOE is updating the current Federal test procedure for CAC/HPs at appendix M1 consistent with the relevant industry consensus test procedure, AHRI 210/240–2024. DOE is also establishing a new Federal test procedure at 10 CFR part 430, subpart B, appendix M2, consistent with the new industry consensus test procedure, AHRI 1600–2024. Appendix M2 would not be required for use until the compliance date of amended standards for CAC/HPs. DOE is also amending its

representation and enforcement provisions for CAC/HPs.

1. Appendix M1

In the April 2024 NOPR, DOE proposed to incorporate by reference AHRI 210/240–202X Draft and relevant industry standards referenced in AHRI 210/240–202X Draft at appendix M1. 89 FR 24206, 24244. DOE also proposed to amend certain provisions for representations and enforcement in 10 CFR part 429, consistent with the changes proposed to the test procedure. *Id.* DOE noted that the proposed revisions to appendix M1 would retain the current efficiency metrics (*i.e.,* EER2, SEER2, and HSPF2). *Id.* DOE walked through the anticipated compliance costs associated with the proposed test procedure at appendix M1 and tentatively determined that proposed amendments would not result in an increase in testing cost relative to the current test procedure. *Id.* DOE also 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. *Id.* DOE requested comment on these tentative determinations under Issue 5 of the April 2024 NOPR. *Id.*

In response, Lennox was supportive of DOE's tentative determinations, commenting that it believes the proposed appendix M1 amendments in the April 2024 NOPR should result in a test procedure that is not unduly burdensome to conduct, consistent with EPCA statutory requirements. (Lennox, No. 24 at p. 6) While less supportive overall, Carrier commented that it agrees the proposed amendments to appendix M1 in the April 2024 NOPR would not result in any retesting or any increase in testing cost for a typical CAC/HP. (Carrier, No. 29 at p. 5) In addition, Carrier asserted that test costs and burden would increase, however, for certain products as a result of the proposed CVP- and CCHP-related provisions. (*Id.*)

In addition to Carrier, Rheem and LG were also less supportive of DOE's tentative determinations, citing the additional test costs and burden associated with CVP testing. (Carrier, No. 29 at p. 5; LG, No. 38 at p. 3; Rheem, No. 34 at p. 7) More specifically, Rheem commented that additional costs associated with the proposed test procedure will stem from modifications to psychrometric test cells in order to comply with the CVP. (Rheem, No. 34 at p. 7) LG commented that an extensive amount of time and associated costs are necessary to conduct CVP testing. (LG, No. 38 at p. 3) LG asserted that, in addition to 30 minutes of stabilization time, it takes a minimum of 11.5 hours and a maximum of 20.5 hours for the cooling CVP test, and a minimum of 16.5 hours and a maximum of 28.5 hours for the CCHP heating CVP test, resulting in third-party testing costs between 13,000 and 24,000 U.S. dollars. (*Id.*)

In response to the Carrier, Rheem, and LG comments regarding additional test costs and burden associated with the CVP, DOE reiterates that the proposed CVP for variable-capacity compressor systems in appendix I of AHRI 210/240–2024 is not mandatory for manufacturers to perform. In the April 2024 NOPR, DOE also noted that, 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 CVP and subsequently rerun the regulatory tests. 89 FR 24206, 24244–24245. However, having no strong evidence to the contrary, DOE noted it expects that current variable-capacity certifications are generally consistent with system performance. *Id.* As such, DOE concluded that any such cost to verify performance and potentially retest is negligible. *Id.*

In response to Carrier's comment regarding additional test costs and burden associated with CCHP provisions (*i.e.,* the required $H4_2$ test for products claimed as CCHPs), DOE reiterates that a manufacturer's claim of CCHP status for its product is optional. 89 FR 24206, 24244–24245. DOE also reiterates that it anticipates products choosing to certify as CCHPs are most likely to be already testing at the 5 °F condition, and hence have no added costs or test burden associated with them. *Id.*

In this final rule, DOE is updating the incorporation by reference to AHRI 210/240–2024, the finalized version of AHRI 210/240–202X Draft. DOE is also referencing the relevant industry standards referenced in AHRI 210/240–2024 at appendix M1. As noted earlier, there are no substantial differences between AHRI 210/240–2024 and AHRI 210/240–202X Draft. As such, DOE's assessment of test procedure costs for appendix M1 are consistent with the April 2024 NOPR.

DOE has determined that the amendments to appendix M1 and the 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 determined that the amendments would not result in an increase in testing cost from the current test procedure. The revisions to the test procedure in appendix M1 for measuring EER2, SEER2, and HSPF2 per AHRI 210/240–2024 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 concluded that the 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.[72]

2. Appendix M2

In the April 2024 NOPR, DOE proposed to incorporate by reference AHRI 1600–202X Draft and relevant industry standards referenced in AHRI 1600–202X Draft at appendix M2. 89 FR 24206, 24245. DOE also proposed to establish provisions for determining SCORE and SHORE, the new efficiency metrics applicable to appendix M2. *Id.* DOE walked through the anticipated compliance costs associated with the proposed test procedure at appendix M2 and tentatively determined that proposed amendments would not result in an increase in testing cost relative to the current test procedure. *Id.* DOE tentatively concluded that the proposed revisions to the test procedure in appendix M2 would change efficiency ratings for CAC/HPs—however, DOE noted 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. *Id.* DOE requested comment

[72] 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.

on these tentative determinations under Issue 6 of the April 2024 NOPR. *Id.*

In response, Lennox was supportive of DOE's tentative determinations, commenting that it believes the proposed appendix M2 in the April 2024 NOPR should result in a test procedure that is not unduly burdensome to conduct, consistent with EPCA statutory requirements. (Lennox, No. 24 at p. 6) Carrier agreed that the proposed appendix M2 in the April 2024 NOPR would not result in any increase in testing cost for a typical CAC/HP from the proposed appendix M1. (Carrier, No. 29 at p. 6) Rheem commented that it is not aware of available data to support the use of a different cost basis for appendix M2 testing. (Rheem, No. 34 at p. 7)

In this final rule, DOE is updating the incorporation by reference to AHRI 1600–2024, the finalized version of AHRI 1600–202X Draft. DOE is also referencing the relevant industry standards referenced in AHRI 210/240–2024 at appendix M1. As noted earlier, there are no substantial differences between AHRI 1600–2024 and AHRI 1600–202X Draft. As such, DOE's assessment of test procedure costs for appendix M2 are consistent with the April 2024 NOPR.

DOE has determined that the amendments to appendix M2 and the 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 determined that the amendments would not result in an increase in testing cost from the current test procedure. The revisions to the test procedure in appendix M2 for measuring EER2, SCORE, and SHORE per AHRI 1600–2024 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 to range from $10,800 to $19,800, depending on the configuration of the CAC/HP (single-stage, two-stage, variable-capacity). DOE has 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.

K. Effective, Compliance, and Other Required Use Dates

The effective date for the adopted test procedure amendment will be 30 days after publication of this final rule in the **Federal Register**. EPCA prescribes that all representations of energy efficiency and energy use, including those made on marketing materials and product labels must be made in accordance with an amended test procedure, beginning 180 days after publication of the final rule in the **Federal Register**. (42 U.S.C. 6293(c)(2)) However, CAC/HPs are not required to be tested according to the test procedure in appendix M2 (that relies on the SCORE and SHORE metrics) until the compliance date of amended energy conservation standards denominated in terms of SCORE and SHORE, should DOE adopt such standards.

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.*) To the extent the modified test procedure adopted in this final rule is required only for the evaluation and issuance of updated efficiency standards, compliance with the amended test procedure does not require use of such modified test procedure provisions until the compliance date of updated standards.

Upon the compliance date of test procedure provisions in this final rule 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 are 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 adopted in this document pertain to issues addressed by waiver granted to Samsung (88 FR 36558, Case No. 2022–009), as discussed in section III.E.4 of this final rule. To the extent that such interim waiver permits 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 adopted in this final rule 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.*) The 72-hour break-in period permitted to the specific VSS systems listed in JCI's interim waiver is unique to the CAC/HP market, and DOE continues to assess whether there is a generalizable need for an extended break-in period for certain VSS systems beyond the specific basic models subject to the interim waiver granted to JCI. As such, DOE is not amending the test procedure to address the issues presented in the interim waiver granted to JCI at this time. 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.

Additionally, as discussed in section III.E.7 of this final rule, DOE recognizes that stakeholders have requested clarification regarding the interaction of EPA's refrigerant regulations and DOE's certification and rating requirements for CAC/HPs. See table III–5 for a consolidated summary of the interaction of DOE's OUWNM certification and rating requirements under the EPA regulations timeline.

TABLE III–5—SUMMARY OF CERTIFICATION AND RATING REQUIREMENT TIMELINES

Indoor or outdoor unit manufactured or imported	Distributed as	Outdoor units with >700 GWP refrigerant	Indoor units with >700 GWP refrigerant
Before 1/1/2025	Matched System	Per EPA, matched systems can be installed prior to January 1, 2026 as long as they were manufactured prior January 1, 2025.	
	.....	Must be certified/rated in combinations with indoor units as distributed in commerce before 1/1/2025 and the matched system must comply with applicable standard; *i.e.,* do not need to be certified/rated as OUWNM.	Must be certified/rated in combinations with outdoor units distributed in commerce before 1/1/2025 and the matched system must comply with the applicable standard.
	Indoor Unit or Outdoor Unit.	Per EPA, indoor and outdoor units can also be installed as replacement units on or after January 1, 2025.	
On or after 1/1/2025	Matched System	Per EPA, matched systems can no longer be installed on or after January 1, 2026.	
	Indoor Unit or Outdoor Unit.	Per EPA, indoor and outdoor units can be installed only as replacement units on or after January 1, 2026.	
		Must be certified/rated and as OUWNM and comply with the applicable standard. Re-certification/rerating required if previous ratings were matched combinations. No new certification of matched systems allowed.	Must be certified/rated in combinations with outdoor units distributed in commerce before 1/1/2025 and the matched system must comply with the applicable standard. No new certification of matched systems allowed.

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 amended by 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 this preamble, this final 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 final 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 a final regulatory flexibility analysis (''FRFA'') for any final rule where the agency was first required by law to publish a proposed rule 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 final rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. DOE has concluded that this rulemaking will not have a significant impact on a substantial number of small entities. Compliance with this test procedure is not required unless and until new energy conservation standards are established for covered CAC/HPs—accordingly, there are no compliance costs stemming directly from this rulemaking.

Still, although it is not required, DOE has undertaken a review of CAC/HP small business manufacturers and, in the following, is presenting the costs that those business may expect if testing on the basis of this test procedure were required in the future.

1. Estimated Number of Small Entities

For the April 2024 NOPR, DOE conducted a focused inquiry into small business manufacturers of the products covered by this rulemaking. DOE used the SBA's small business size standards to determine whether any small entities would be subject to the requirements of the rule. The size standards are listed by North American Industry Classification System (''NAICS'') code as well as by industry description and are available at *www.sba.gov/document/support-table-size-standards.* Manufacturing CAC/HPs is classified under NAICS 333415, ''Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing.'' The SBA sets a threshold of 1,250 employees or fewer for an entity to be considered as a small business for this category. DOE used available public information to identify potential small manufacturers. DOE accessed the Compliance Certification Database [73] (''CCD''), the Modernized Appliance Efficiency Database System [74] (''MAEDbS''), and the National Resources Canada database [75] (''NRCan'') to create a list of companies that import or otherwise manufacture the products covered by this final rule. Once DOE created a list of potential manufacturers, DOE used market research tools to determine whether any met the SBA's definition of a small entity—based on the total number of employees for each company including parent, subsidiary, and sister entities—and gather annual revenue estimates.

Based on DOE's analysis, DOE identified 23 OEMs manufacturing CAC/HPs covered by this test procedure. DOE screened out companies that do not meet the small entity definition and, additionally, screened out companies that are largely or entirely foreign owned and operated. Of the 23 OEMs identified OEMs, six were identified as domestic small businesses. DOE did not receive comments on the April 2024 NOPR in regard to its estimate of domestic small businesses.

2. Estimate of Small Business Testing Costs

This final rule adopts updated industry test standards for CAC/HPs. DOE is updating the current Federal test procedure for CAC/HPs at appendix M1 consistent with the finalized version of the relevant industry consensus test procedure, AHRI 210/240–2024. DOE is also proposing a new Federal test procedure at 10 CFR part 430, subpart B, appendix M2, consistent with the finalized version of the industry consensus test procedure, AHRI 1600–2024. 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 is incorporating by reference AHRI 210/240–2024 for CAC/HPs and to amend certain provisions for representations and enforcement in 10 CFR part 429, consistent with the changes to the test procedure. 89 FR 24206, 24244. The revisions to appendix M1 would retain the previous test procedure's efficiency metrics—EER2, SEER2, and HSPF2. The testing requirements in appendix M1 are generally consistent with those in AHRI 210/240–2024, which in turn references ANSI/ASHRAE 37–2009, ANSI/ASHRAE 16–2016, and ANSI/ASHRAE 116–2010. This 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 Controls Verification Procedure (''CVP'') for variable-capacity compressor systems in appendix I of AHRI 210/240–2024 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 determination of cut-in and cut-out temperatures in appendix J of the AHRI 210/240–2024 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 concluded that the revisions to the test procedure in appendix M1 would not change efficiency ratings for CAC/HPs, and therefore would not require retesting as a result of DOE's adoption of this amendment to the test procedure.[76] Further, the test procedure in appendix M1 would not increase third-party laboratory testing costs per unit; DOE estimates that the costs for physical testing prior to these amendments would 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 is establishing a new test procedure that references the industry test procedure, AHRI 1600–2024, for measuring new efficiency metrics, SCORE and SHORE. 89 FR 24204, 23245. Appendix M2 will 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 testing requirements in appendix M2 are generally consistent with those in AHRI 1600–2024, which in turn references ANSI/ASHRAE 37–2009, ANSI/ASHRAE 16–2016, and ASHRAE 116–2010. This revision to the test procedure in appendix M2 for measuring EER, SCORE, and SHORE is not expected to increase third-party laboratory testing costs per unit relative to the prior DOE test procedure. The standby and off-mode power consumption of auxiliary components is determined using appendix G of AHRI 1600–2024 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 will not result in increased testing costs as compared to the previous test procedure. The other amendments—which include (a) building load lines and temperature bin hours for calculation of SCORE and SHORE, (b)

[73] U.S. Department of Energy Compliance Certification Management System, available at *www.regulations.doe.gov/ccms* (last accessed July 30, 2023).

[74] California Energy Commission's Modernized Appliance Efficiency Database System, available at *cacertappliances.energy.ca.gov/Login.aspx.* (Last accessed Sept. 22, 2023).

[75] Natural Resources Canada searchable product list, available at *oee.nrcan.gc.ca/pml-lmp/* (last accessed Sept 19, 2023).

[76] 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.

default fan power coefficients for coil-only systems, and (c) air flow limits to address inadequate dehumidification—also will not affect testing costs.

The overall testing cost is not expected to increase with appendix M2. DOE estimates the costs of physical testing for the new metrics SCORE and SHORE to range from $10,800 to $19.800, depending on the configuration of the CAC/HP (single-stage, two-stage, variable-capacity). Additionally, DOE allows the use of AEDMs. The use of an AEDM is expected to be less costly than physical testing of large numbers of CAC/HP models; DOE estimates the cost to develop an AEDM to be $19,383 per AEDM for a basic model, which includes the cost of physical testing done at a third-party laboratory to validate the AEDM.[77] 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 five minutes of an engineer's time 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 1600–2024, the industry test procedure DOE is referencing 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 possible future energy conservation standards rulemaking. Accordingly, DOE has determined that the test procedure amendments would not add any additional testing burden to manufacturers—including the six domestic small manufacturers.

3. Certification Statement

Based on the de minimis cost impacts, DOE certifies that this final rule does not have a ''significant economic impact on a substantial number of small entities,'' and determined that the preparation of a FRFA is not warranted. DOE will transmit a certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the Small Business Administration for review under 5 U.S.C. 605(b).

C. Review Under the Paperwork Reduction Act of 1995

Manufacturers of CAC/HPs must certify to DOE that their products comply with any applicable energy conservation standards. To certify 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 amending the certification or reporting requirements for CAC/HPs in this final rule. Instead, DOE may consider proposals to amend the certification requirements and reporting for CAC/HPs under a separate rulemaking regarding appliance and equipment certification. 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 final rule, DOE establishes test procedure amendments that it expects will be used to develop and implement future energy conservation standards for CAC/HPs. DOE has determined that this 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, appendix A to subpart D, 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 on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE examined this final rule and determined that it will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this final 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 (February 7, 1996), imposes on Federal agencies the general duty to adhere to the following requirements: (1) eliminate drafting errors and ambiguity, (2) write regulations to minimize litigation, (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification

[77] DOE estimates that a mechanical engineer would take 60 hours to create an AEDM. The fully burdened wage of a mechanical engineer is 68.05 based on an unburdened median wage of $47.84 and on wages representing 70.3 percent of labor costs. Average cost of third-party testing would be $14,400 given the previously described range of costs. See *www.bls.gov/oes/current/oes172141.htm* for the wage figure and *www.bls.gov/news.release/archives/ecec_06182024.pdf* for the wage percentage of labor costs figure.

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, this final 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 regulatory action resulting 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 final 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 proposed rule or policy that may affect family well-being. When developing a Family Policymaking Assessment, agencies must assess whether: (1) the action strengthens or erodes the stability or safety of the family and, particularly, the marital commitment; (2) the action strengthens or erodes the authority and rights of parents in the education, nurture, and supervision of their children; (3) the action helps the family perform its functions, or substitutes governmental activity for the function; (4) the action increases or decreases disposable income or poverty of families and children; (5) the proposed benefits of the action justify the financial impact on the family; (6) the action may be carried out by State or local government or by the family; and whether (7) the action establishes an implicit or explicit policy concerning the relationship between the behavior and personal responsibility of youth, and the norms of society. In evaluating the above factors, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment as none of the above factors are implicated. Further, this determination would not have any financial impact on families nor any impact on the autonomy or integrity of the family as an institution.

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 regulation will 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 final 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 significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that: (1) is a significant regulatory action under Executive Order 12866, or any successor order, and is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) is designated by the Administrator of OIRA as a significant energy action. For any significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use if the regulation is implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

This regulatory action 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 modifications to the test procedure for CAC/HPs adopted in this final rule incorporates testing methods contained in certain sections of the following commercial standards: AHRI 210/240–2024, AHRI 1600–2024, 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 they were developed in a manner that fully provides for public participation, comment, and review.) DOE has consulted with both the Attorney General and the Chairman of the FTC about the impact on competition of using the methods contained in these standards and has received no comments objecting to their use.

M. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this rule before its effective date. The report will state that it has been determined that the rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

N. Description of Materials Incorporated by Reference

In this final rule, DOE incorporates by reference the following test standards:

AHRI 210/240–2024. This test standard is an update to AHRI 210/240–2023 (2020), an industry-accepted test procedure for measuring the performance of Unitary Air-source Air-conditioners & Heat Pump Equipment. The revised appendix M1 will be consistent with provisions in AHRI 210/240–2024.

AHRI 1600–2024. This test standard is a major update to AHRI 210/240–2023 (2020), introducing new seasonal cooling and heating efficiency metrics, namely SCORE and SHORE. The new appendix M2 will be consistent with provisions in AHRI 210/240–2024.

Copies of AHRI 210/240–2024 and AHRI 1600–2024 can be obtained from AHRI, 2311 Wilson Blvd., Suite 400, Arlington, VA 22201, (703) 524–8800, or found online at *www.ahrinet.org.*

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. 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.

ANSI/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 ASHRAE 37–2009, ANSI/ASHRAE 16 and ANSI/ASHRAE 116–2010 are available on ASHRAE's website at *www.ashrae.org.*

The following standards were previously approved for incorporation by reference in the regulatory sections where they appear, and no changes are made: AHRI 210/240–2008, AHRI 1160, and ANSI 1230–2010.

V. Approval of the Office of the Secretary

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

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 December 18, 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 December 19, 2024.

Treena V. Garrett,

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

For the reasons stated in the preamble, DOE amends 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. Revising paragraphs (a) and (c) introductory text;

■ b. Redesignating paragraphs (c)(2) through (7) as paragraphs (c)(3) through (8); and

■ c. Adding new paragraph (c)(2) and paragraph (c)(9).

The revisions and additions read as follows:

§ 429.4 Materials incorporated 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 U.S. Department of Energy (DOE) 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 Department of Energy (DOE) and at the National Archives and Records Administration (NARA). Contact DOE at: The U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121; (202) 586–9127; *Buildings@ee.doe.gov; www.energy.gov/eere/buildings/appliance-and-equipment-standards-program.* 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.

* * * * *

(c) *AHRI.* Air-Conditioning, Heating, and Refrigeration Institute, 2311 Wilson Blvd., Suite 400, Arlington, VA 22201, (703) 524–8800, or go to: *www.ahrinet.org.*

* * * * *

(2) AHRI Standard 210/240–2024 (I–P), (''AHRI 210/240–2024''), Performance Rating of Unitary Air-conditioning and Air-source Heat Pump Equipment, copyright 2024; IBR approved for § 429.134.

* * * * *

(9) AHRI Standard 1600–2024 (I–P), (''AHRI 1600–2024''), Performance Rating of Unitary Air-conditioning and Air-source Heat Pump Equipment, copyright 2024; IBR approved for § 429.134.

* * * * *

■ 3. Amend § 429.16 by revising paragraphs (a)(1) and (2), (a)(3)(i), (b)(2), (b)(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, EER, 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).	

TABLE 1 TO PARAGRAPH (a)(1)—Continued

Category	Equipment subcategory	Required represented values
	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) * * *

(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 1 to 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) *Individual model/combination selection for testing.* (i) Table 2 to this paragraph (b)(2)(i) 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 table 2, 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 10 CFR part 430). or seasonal cooling and off-mode rating. efficiency (SCORE) (when testing. in accordance with appendix M2 to subpart.. B of 10 CFR 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.

TABLE 2 TO PARAGRAPH (b)(2)(i)—Continued

Category	Equipment subcategory	Must test:	With:
	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 10 CFR part 430) or SCORE combination (when testing under appendix M2 to subpart B of 10 CFR 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 10 CFR part 430) or SCORE (when testing under appendix M2 to subpart B of 10 CFR part 430) represented value, the ICM may select one for testing purposes.
	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 10 CFR part 430) or SCORE combination (when testing under appendix M2 to subpart B of 10 CFR 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 10 CFR part 430) or SCORE represented value (when testing under appendix M2 to subpart B of 10 CFR 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 10 CFR part 430); or meeting the requirements of section 3 of appendix M2 (when testing under appendix M2 to subpart B of 10 CFR part 430).

(ii) When testing in accordance with appendix M1 to subpart B of 10 CFR part 430, each individual model/combination (or ''tested combination'') identified in table 2 to 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 10 CFR part 430 and determining SCORE and SHORE, each individual model/combination (or ''tested combination'') identified in table 2 to 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) *EER2, SEER2, HSPF2, SCORE, EER, 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 Student's t-Distribution Value for a 90 percent one-tailed confidence interval with n-1 degrees of freedom (from appendix A to this subpart). Round represented values of EER2, SEER2, HSPF2, EER, 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 10 CFR 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 10 CFR part 430, or appendix M2 to subpart B of 10 CFR 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 10 CFR part 430, or appendix M2 to subpart B of 10 CFR 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 10 CFR part 430, or appendix M2 to subpart B of 10 CFR 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 10 CFR 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 EER2, SEER2, HSPF2, EER, SCORE and 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 10 CFR 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 10 CFR 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 10 CFR 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)(iii) 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 10 CFR 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)(iii) 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 10 CFR 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 10 CFR 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 cooling 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)(iii)(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)(iii) 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)(iii) 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 10 CFR 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 (EER2, SEER2, HSPF2, SCORE, EER, 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 (EER2, SEER2, HSPF2, EER, 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 July 7, 2025, 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 July 7, 2025, 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 10 CFR part 430, or SCORE or SHORE when testing in accordance with appendix M2 to subpart B of 10 CFR 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 10 CFR 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 10 CFR 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 210/240–2024 (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 10 CFR 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 10 CFR 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 1600–2024 (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 10 CFR part 430 or appendix M2 to subpart B of 10 CFR 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 10 CFR part 430, the cut-out and cut-in temperatures may be verified using the method in appendix J of AHRI 210/240–2024 (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 10 CFR part 430, the cut-out and cut-in temperatures may be verified using the method in appendix J of AHRI 1600–2024 (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 (CVP).* A 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 10 CFR part 430 or appendix M2 to subpart B of 10 CFR 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 10 CFR part 430 or, appendix M2 to subpart B of 10 CFR part 430, as applicable.

(A) *When testing in accordance with appendix M1 to subpart B of 10 CFR part 430.* The CVP will be conducted per appendix I of AHRI 210/240–2024 (incorporated by reference, see § 429.4).

(B) *When testing in accordance with appendix M2 to subpart B of 10 CFR part 430.* The CVP will be conducted per appendix I of AHRI 1600–2024 (incorporated by reference, see § 429.4).

(C) *Variable capacity certified, single capacity systems.* 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, EER 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 (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, EER 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 (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, EER 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 (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 210/240–2024 (if testing in accordance with appendix M1 to subpart B of 10 CFR part 430; (incorporated by reference, see § 429.4)) or of AHRI 1600–2024 (if testing in accordance with appendix M2 to subpart B of 10 CFR part 430; (incorporated by reference, see § 429.4)), with the exception that indoor entering wet bulb deviation in I5.1 and test operating tolerance in I5.1.3 is applicable only for cooling mode CVP.

(*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 of the two successive test period sub-intervals 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 successive test period 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 (*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) Determine whether the measured capacity for each full load interval, as evaluated per the CVP conducted in paragraph (k)(4)(i)(A) or (B) of this section, is no more than 6% less than the corresponding certification test capacity, as follows:

$$\text{Cooling full: } \frac{\dot{q}_{A,Full} - \dot{q}_{CVP,A,Full}}{\dot{q}_{A,Full}} \times 100 \leq 6.0$$

$$\text{Heating full (17°F): } \frac{\dot{q}_{H3,Full} - \dot{q}_{CVP,H3,Full}}{\dot{q}_{H3,Full}} \times 100 \leq 6.0$$

$$\text{Heating full (5°F): } \frac{\dot{q}_{H4,Full} - \dot{q}_{CVP,H4,Full}}{\dot{q}_{H4,Full}} \times 100 \leq 6.0$$

Where:

$\dot{q}_{A,Full}$ = Certification test capacity at A_{Full} condition,

$\dot{q}_{CVP,A,Full}$ = CVP test capacity at A_{Full} condition,

$\dot{q}_{H3,Full}$ = Certification test capacity at $H3_{Full}$ condition,

$\dot{q}_{CVP,H3,Full}$ = CVP test capacity at $H3_{Full}$ condition,

$\dot{q}_{H4,Full}$ = Certification test capacity at $H4_{Full}$ condition,

$\dot{q}_{CVP,H4,Full}$= CVP test capacity at $H4_{Full}$ condition,

(C) Determine whether the measured capacity for each minimum load interval, as evaluated per the CVP conducted in paragraph (k)(4)(i)(A) or (B) of this section, is no more than 6% less than the corresponding certification test capacity, as follows:

$$\text{Cooling minimum: } \frac{\dot{q}_{CVP,F,Low} - \dot{q}_{F,Low}}{\dot{q}_{A,Full}} \times 100 \leq 6.0$$

$$\text{Heating minimum: } \frac{\dot{q}_{CVP,H1,Low} - \dot{q}_{H1,Low}}{\dot{q}_{H3,Full}} \times 100 \leq 6.0$$

Where:

$\dot{q}_{CVP,F,Low}$= CVP test capacity at F_{Low} condition,

$\dot{q}_{F,Low}$ = Certification test capacity at F_{Low} condition,

$\dot{q}_{CVP,H1,Low}$ = CVP test capacity at $H1_{Low}$ condition,

$\dot{q}_{H1,Low}$= Certification test capacity at $H1_{Low}$ condition,

(D) Determine whether the measured efficiency for the full and minimum load interval, as evaluated per the CVP conducted in paragraph (k)(4)(i)(A) or (B) of this section, is no more than 10% less than the corresponding certification test efficiency, as follows:

$$\text{Cooling full: } \frac{EER2_{A,Full} - EER2_{CVP,A,Full}}{EER2_{A,Full}} \times 100 \leq 10.0$$

$$\text{Cooling minimum: } \frac{EER2_{F,Low} - EER2_{CVP,F,Low}}{EER2_{F,Low}} \times 100 \leq 10.0$$

$$\text{Heating full (5°F): } \frac{COP2_{H4,Full} - COP2_{CVP,H4,Full}}{COP2_{H4,Full}} \times 100 \leq 10.0$$

$$\text{Heating full (17°F): } \frac{COP2_{H3,Full} - COP2_{CVP,H3,Full}}{COP2_{H3,Full}} \times 100 \leq 10.0$$

$$\text{Heating minimum: } \frac{COP2_{H1,Low} - COP2_{CVP,H1,Low}}{COP2_{H1,Low}} \times 100 \leq 10.0$$

(E) Cooling and heating efficiency requirements are shown using EER2 and COP2 to align with testing in accordance with appendix M1 to subpart B of 10 CFR part 430. When testing in accordance with appendix M2 to subpart B of 10 CFR part 430, replace EER2 with EER, and COP2 with COP.

(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) through (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, EER 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) through (D) of this section, the unit shall be tested per instructions in paragraphs (k)(4)(v)(A) through (C) of this section, as applicable. The instructions in paragraphs (k)(4)(v)(A) through (C) shall be followed, as applicable, only for the certification tests corresponding to the out of tolerance compressor speed interval based on the evaluations of paragraphs (k)(4)(iii)(B) through (D). For all compressor speed intervals for which the capacity and EER2/COP2/EER/COP are in tolerance as per paragraphs (k)(4)(iii)(B) through (D), 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 (B) of this section is used as the means for overriding the controls, and both of the following are supported by the control device: monitoring of the compressor and indoor blower speed during native-control operation without otherwise impacting the control of the system; and 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.

(*1*) The compressor and indoor blower speed shall be monitored during the CVP conducted in paragraph (k)(4)(i)(A) or (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) of this section 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 210/240–2024 (if testing in accordance with appendix M1 to subpart B of 10 CFR part 430; (incorporated by reference, see § 429.4)) or of AHRI 1600–2024 (if testing in accordance with appendix M2 to subpart B of 10 CFR part 430; (incorporated by reference, see § 429.4)), 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 table 1 to this paragraph (k)(4)(v)(A). 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 (C) of this section are not met or the efficiency tolerances of paragraph (k)(4)(iii)(D) of this section 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.

(*2*) 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 210/240–2024 (if testing in accordance with appendix M1 to subpart B of 10 CFR part 430; (incorporated by reference, see § 429.4)) or of AHRI 1600–2024 (if testing in accordance with appendix M2 to subpart B of 10 CFR part 430; (incorporated by reference, see § 429.4)) and for use in calculating performance at 35 °F. If required, the adjusted $H1_{Low}$ and $H3_{Low}$ 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 210/240–2024 (if testing in accordance with appendix M1 to subpart B of 10 CFR part 430; (incorporated by reference, see § 429.4)) or of AHRI 1600–2024 (if testing in accordance with appendix M2 to subpart B of 10 CFR part 430; (incorporated by reference, see § 429.4)). 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}.
$H1_{Low}$	N/A	$H0_{Low}$, $H1_{Low}$, $H3_{Low}$	$H0_{Low}$, $H1_{Low}$.
$H3_{Full}$	$H2_{Full}$, $H3_{Full}$	$H3_{Full}$	$H3_{Full}$.
$H4_{Full}$	$H4_{Full}$	$H4_{Full}$	$H4_{Full}$.

(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 to paragraph (k)(4)(v)(A) of this section for which either the capacity tolerances of paragraph (k)(4)(iii)(B) or (C) of this section are not met or the efficiency tolerances of paragraph (k)(4)(iii)(D) of this section 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.

(*1*) 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 (with no adjustment for tests having a CVP interval). For the certification tests requiring adjustment with no CVP interval (any required certification test in column 2, 3, or 4 of table 1 to paragraph (k)(4)(v)(A) of this section other than A_{Full}, F_{Low}, $H1_{Low}$, $H3_{Full}$ and $H4_{Full}$ for which the column 1 CVP interval did not meet capacity or EER2/COP2/EER/COP tolerances), 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 power measured during the CVP test interval divided by the power 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:

$$P_{B,Full} = P_{B,Full,Certification} \times \frac{P_{CVP,A,Full}}{P_{A,Full,Certification}}$$

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:

$$P_{B,Low} = P_{B,Low,Certification} \times \frac{P_{CVP,F,Low}}{P_{F,Low,Certification}}$$

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:

$$P_{H0,Low} = P_{H0,Low,Certification} \times \frac{P_{CVP,H1,Low}}{P_{H1,Low,Certification}}$$

$$P_{H3,Low} = \frac{P_{CVP,H1,Low}}{(1 + 30 \cdot PSF)}$$

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

(*2*) 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 210/240–2024 (if testing in accordance with appendix M1 to subpart B of 10 CFR part 430; (incorporated by reference, see § 429.4)) or of AHRI 1600–2024 (if testing in accordance with appendix M2; (incorporated by reference, see § 429.4)), and for use in calculating performance at 35 °F. If required, the measured $H1_{Low}$ from the CVP and the adjusted $H3_{Low}$ 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 210/240–2024 (if testing in accordance with appendix M1 to subpart B of 10 CFR part 430; (incorporated by reference, see § 429.4)) or of AHRI 1600–2024 (if testing in accordance with appendix M2 to subpart B of 10 CFR part 430; (incorporated by reference, see § 429.4)). No adjustments are required for intermediate or nominal compressor speed tests or, if cyclic tests are conducted, the degradation coefficient(s).

(C) 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 and is not certified or marketed for use with only a proprietary control device 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 § 430.2 by revising the definition of ''Central air conditioner or central air conditioning heat pump'' to read as follows.

§ 430.2 Definitions.

* * * * *

Central air conditioner or central air conditioning heat pump means a product, other than a packaged terminal air conditioner, packaged terminal heat pump, single-phase single-package vertical air conditioner with cooling capacity less than 65,000 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 § 431.92 of this chapter, which is powered by single phase electric current, air cooled, rated below 65,000 Btu per hour, not contained within the same cabinet as a furnace, the rated capacity of which is above 225,000 Btu per hour, 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).

* * * * *

■ 8. Amend § 430.3 by:

■ a. Removing ''appendices M and M1'' and adding in its place ''appendix M'' in paragraph (b)(4) introductory text;

■ b. Revising paragraphs (c) and (g)(1) through (3);

■ c. Removing ''appendices M and M1'' and adding in its place ''appendix M'' in paragraphs (g)(4) introductory text and (g)(21);

■ d. Redesignating paragraphs (g)(22) through (24) as paragraphs (g)(23) through (25); and

■ e. Adding new paragraph (g)(22).

The revisions and addition read as follows:

§ 430.3 Materials incorporated by reference.

* * * * *

(c) *AHRI.* Air-Conditioning, Heating, and Refrigeration Institute, 2311 Wilson Blvd., Suite 400, Arlington, VA 22201, (703) 524–8800, or go to: *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 210/240–2024 (I–P), (''AHRI 210/240–2024''), Performance Rating of Unitary Air-conditioning and Air-source Heat Pump Equipment; 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 Standard 1600–2024 (I–P) (''AHRI 1600–2024''), Performance Rating of Unitary Air-conditioning and Air-source Heat Pump Equipment; IBR approved for appendix M2 to subpart B.

* * * * *

(g) * * *

(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 CC, CC1, M1, and M2 to subpart B.

* * * * *

(22) ANSI/ASHRAE Standard 116–2010, (''ANSI/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.

* * * * *

■ 9. 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 5 of appendix M1 to this subpart or seasonal cooling and off-mode rating efficiency (SCORE) as described in sections 2 and 4 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 energy efficiency ratio (EER) as described in section 2 of appendix M2 to this subpart and round off to the nearest 0.025 Btu/W-h. EER2 (for appendix M1 to this subpart) or EER (for appendix M2 to this subpart) 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 5 of appendix M1 to this subpart or seasonal heating and off-mode rating efficiency (SHORE) as described in sections 2 and 4 of appendix M2 to this subpart, and round off to the nearest 0.025 Btu/W-h.

(5) Determine $P_{W,OFF,}$ 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.

* * * * *

■ 10. Revise appendix M1 to subpart B of part 430 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 July 7, 2025, 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 M1.

Beginning July 7, 2025, 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 210/240–2024, ANSI/ASHRAE 16, ASHRAE 37–2009 and ANSI/ASHRAE 116–2010. However, certain enumerated provisions of AHRI 210/240–2024, ANSI/ASHRAE 16, 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 210/240–2024

(a) Section 1 Purpose is inapplicable,
(b) Section 2 Scope is inapplicable,
(c) The following subsections of Section 3 Definitions are inapplicable: 3.2.16 (Double-duct system), 3.2.20 (Gross capacity), 3.2.46 (Oil Recovery Mode), 3.2.51 (Published Rating), 3.2.63 (Standard Filter), 3.2.78 (Unitary Air-conditioner), 3.2.79 (Unitary Heat Pump),
(d) Section 4 Classifications is inapplicable,
(e) The following subsection of Section 5 Test Requirements is inapplicable: 5.1.6.2 (Outdoor Unit with No Match (OUWNM)),
(f) The following subsections of Section 6 Rating Requirements are inapplicable: 6.1.8, 6.2, 6.3, 6.4 and 6.5
(g) Section 7 Minimum Data Requirements for Published Ratings is inapplicable,
(h) Section 8 Operating Requirements is inapplicable,
(i) Section 9 Marking and Nameplate Data is inapplicable,
(j) Section 10 Conformance Conditions is inapplicable,
(k) Appendix A References—Normative is inapplicable,
(l) Appendix B References—Informative is inapplicable,
(m) Appendix C Secondary Capacity Check Requirements—Normative is inapplicable,
(n) Appendix F Unit Configurations for Standard Efficiency Determination—Normative is inapplicable,
(o) Appendix H Verification Testing—Normative is inapplicable,
(p) Appendix I Controls Verification Procedure—Normative is inapplicable, and
(q) 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 210/240–2024 and the applicable provisions of ANSI/ASHRAE 16, ASHRAE 37–2009, and ANSI/ASHRAE 116–2010. The A_{Full} (cooling mode) and $H1_{Full}$ or $H1_{Nom}$ (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. For cooling mode tests of variable capacity systems, the compressor shall operate at the same cooling full speed, measured by RPM of power input frequency (Hz), for both A_{Full} and B_{Full} tests. Additionally, the compressor shall operate at the same cooling minimum speed, measured by RPM or power input frequency (Hz), for the B_{Low}, F_{Low}, G_{Low}, and I_{Low} tests.

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 210/240–2024, ASHRAE 37–2009, ANSI/ASHRAE 16 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 210/240–2024.

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 a new Indoor Unit to create a new 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 and global warming potential greater than 150 per EPA regulations in 40 CFR 84.64, 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 210/240–2024. 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 at a single cooling air volume rate 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 210/240–2024). Tested values of CD^c and/or CD^h are not permitted. The default value, 0.25, shall be used for both cooling and heating mode testing.

5. Test Conditions

5.1. Test Conditions for Certifying Compliance with Standards. The following conditions specified in AHRI 210/240–2024 apply when testing to certify to the SEER2 and HSPF2 energy conservation standards in § 430.32(c).

(a) For cooling mode, use the rating conditions specified in table 8 of AHRI 210/240–2024 and the fractional cooling bin hours in table 15 of AHRI 210/240–2024 to determine SEER2, and EER2 for models subject to regional standards in terms of EER2.

(b) For heat pump heating mode, use the rating conditions specified in table 8 of AHRI 210/240–2024 and the fractional heating bin hours specified for Region IV in table 16 of AHRI 210/240–2024 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 210/240–2024 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 210/240–2024 and the fractional heating hours specified for Regions other than Region IV in table 16 of AHRI 210/240–2024 are optional. Representations of COP_{peak} made using appendix K are optional.

■ 11. Add appendix M2 to subpart B of part 430 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 July 7, 2025, 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 July 7, 2025, 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 1600–2024, ANSI/ASHRAE 16, ASHRAE 37–2009, and ANSI/ASHRAE 116–2010. However, certain enumerated provisions of AHRI 1600–2024, ANSI/ASHRAE 16, 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 1600–2024

(a) Section 1 Purpose is inapplicable,
(b) Section 2 Scope is inapplicable,
(c) The following sections of Section 3 Definitions are inapplicable: 3.2.16 (Double-duct system), 3.2.20 (Gross capacity), 3.2.45 (Oil Recovery Mode), 3.2.50 (Published Rating), 3.2.63 (Standard Filter), 3.2.78 (Unitary Air-conditioner), 3.2.79 (Unitary Heat Pump),
(d) Section 4 Classifications is inapplicable,
(e) The following subsection of Section 5 Test Requirements is inapplicable: 5.1.6.2 (Outdoor Unit with No Match (OUWNM)),
(f) The following subsections of Section 6 Rating Requirements are inapplicable: 6.1.8, 6.2, 6.3, 6.4 and 6.5
(g) Section 7 Minimum Data Requirements for Published Ratings is inapplicable,
(h) Section 8 Operating Requirements is inapplicable,
(i) Section 9 Marking and Nameplate Data is inapplicable,
(j) Section 10 Conformance Conditions is inapplicable,
(k) Appendix A References—Normative is inapplicable,
(l) Appendix B References—Informative is inapplicable,
(m) Appendix C Secondary Capacity Check Requirements—Normative is inapplicable,
(n) Appendix F Unit Configurations for Standard Efficiency Determination—Normative is inapplicable,
(o) Appendix H Verification Testing—Normative is inapplicable,
(p) Appendix I Controls Verification Procedure—Normative is inapplicable, and
(q) 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 applicable energy efficiency metrics (SCORE, SHORE, and EER) in accordance with the specified sections of AHRI 1600–2024 and the applicable provisions of ANSI/ASHRAE 16, ASHRAE 37–2009, and ANSI/ASHRAE 116–2010. The A_{Full} (cooling mode) and $H1_{Full}$ or $H1_{Nom}$ (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. For cooling mode tests of variable capacity systems, the compressor shall operate at the same cooling full speed, measured by RPM of power input frequency (Hz), for both A_{Full} and B_{Full} tests. Additionally, the compressor shall operate at the same cooling minimum speed, measured by RPM or power input frequency (Hz), for the B_{Low}, F_{Low}, G_{Low}, and I_{Low} tests.

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 1600–2024, ASHRAE 37–2009, ANSI/ASHRAE 16, 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 a new 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 and a global warming potential greater than 150 per EPA regulations in 40 CFR 84.64, 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 1600–2024. 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 at a single cooling air volume rate 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 1600–2024). Tested values of CD^c and/or CD^h are not permitted. The default value, 0.25, shall be used for both cooling and heating mode testing.

4. Test Conditions

4.1. Test Conditions for Certifying Compliance with Standards. The following conditions specified in AHRI 1600–2024 apply if testing to certify to the SCORE and SHORE energy conservation standards in § 430.32(c).

(a) For cooling mode, use the rating conditions specified in table 8 of AHRI 1600–2024 and the 'U.S. National Average' cooling conditioning hours and shoulder season hours in table 15 of AHRI 1600–2024, to determine SCORE, and EER for models subject to regional standards in terms of EER.

(b) For heat pump heating mode, use the rating conditions specified in table 8 of AHRI 1600–2024 and the 'U.S. National Average' heating conditioning hours and shoulder season hours specified in table 18 of AHRI 1600–2024 to determine the heating efficiency metric, SHORE.

4.2. Optional Representations. Representations of EER made using the rating conditions specified in table 8 of AHRI 1600–2024 are optional for models not subject to regional standards in terms of EER. Representations of SHORE made using the rating conditions specified in table 8 of AHRI 1600–2024 and the 'Cold Climate Average' heating conditioning hours and shoulder season hours in table 18 of AHRI 1600–2024 are optional. Representations of COP_{peak} made using appendix K are optional.

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Part III

Department of Transportation

National Highway Traffic Safety Administration

49 CFR Parts 571 and 585

Federal Motor Vehicle Safety Standards; Child Restraint Systems, Child Restraint Anchorage Systems, Incorporation by Reference; Final Rule

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Parts 571 and 585

[Docket No. NHTSA–2024–0089]

RIN 2127–AL20

Federal Motor Vehicle Safety Standards; Child Restraint Systems, Child Restraint Anchorage Systems, Incorporation by Reference

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule amends Federal Motor Vehicle Safety Standard (FMVSS) No. 225; Child restraint systems, and FMVSS No. 213b; Child restraint systems, to improve ease-of-use of the lower and tether anchorages, improve correct use of child restraint systems in vehicles, and maintain or improve the correct use and effectiveness of child restraint systems (CRSs) in motor vehicles. This final rule fulfills a mandate of the Moving Ahead for Progress in the 21st Century Act (MAP–21) requiring that NHTSA improve the ease-of-use for lower anchorages and tethers in all rear seat positions.

DATES:

Effective date: March 10, 2025.

IBR date: The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register beginning March 10, 2025.

Compliance date: This final rule adopts a 3-year phase-in period to comply with the updated requirements in FMVSS No. 225. The phase-in begins on September 1, 2028, and requires that 20 percent of a manufacturer's applicable vehicles produced from September 1, 2028, to August 31, 2029, comply with the updated FMVSS No. 225, followed by 50 percent from September 1, 2029, to August 31, 2030, and 100 percent on and after September 1, 2030. Early compliance is permitted.

Reconsideration date: If you wish to petition for reconsideration of this rule, your petition must be received by February 21, 2025.

ADDRESSES: Petitions for reconsideration of this final rule must refer to the docket number set forth above and be submitted to the Administrator, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590. Note that all petitions received will be posted without change to *www.regulations.gov,* including any personal information provided.

Confidential Business Information: If you wish to submit any information under a claim of confidentiality, you should submit your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, NHTSA, at the address given under **FOR FURTHER INFORMATION CONTACT**. In addition, you should submit a copy, from which you have deleted the claimed confidential business information, to Docket Management at the address given above. When you send a submission containing information claimed to be confidential business information, you should include a cover letter setting forth the information specified in our confidential business information regulation (49 CFR part 512). Please see further information in the Regulatory Notices and Analyses section of this preamble.

Privacy Act: The petition will be placed in the docket. Anyone is able to search the electronic form of all documents received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR19477–78) or you may visit *www.transportation.gov/individuals/privacy/privacy-act-system-records-notices.*

Docket: For access to the docket to read background documents or comments received, go to *www.regulations.gov,* or the street address listed above. Follow the online instructions for accessing the dockets.

FOR FURTHER INFORMATION CONTACT: For technical issues, you may call Cristina Echemendia, Office of Crashworthiness Standards (phone: 202–366–6345). For legal issues, you may call Natasha Reed, Office of the Chief Counsel (phone: 202–366–2992). The mailing address of these officials is: National Highway Traffic Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Washington, DC 20590.

SUPPLEMENTARY INFORMATION: In accordance with MAP–21 (Pub. L. 112–141), this final rule amends FMVSS No. 225 [1] and 213b [2] to improve the ease-of-use of child restraint anchorage systems. MAP–21 Section 31502 requires the Secretary of Transportation (NHTSA by delegation) to improve the ease-of-use for lower anchorages and tethers in all rear seat seating positions if such anchorages and tethers are feasible. Section 31502 of MAP–21 states that the Secretary must issue a final rule unless such an amendment to FMVSS No. 225 does not meet the requirements and considerations set forth in subsections (a) and (b) of section 30111 of title 49, United States Code (the National Traffic and Motor Vehicle Safety Act (Safety Act)). NHTSA is issuing this final rule, as directed by MAP–21, after determining that the rule meets the requirements and considerations of section 30111(a) and (b) of the Safety Act. This final rule also fulfils NHTSA's goal of improving the usability of child restraint anchorage systems.[3]

NHTSA published the notice of proposed rulemaking (NPRM) preceding this final rule on January 23, 2015 (80 FR 3744). In this final rule preamble, NHTSA is using the term ''child restraint anchorage system'' (CRAS) to refer to the full vehicle system [4] that is designed for attaching a child restraint system (CRS) to a vehicle at a particular designated seating position (DSP).'' [5] NHTSA also uses the term ''lower anchorages'' for the lower anchorage points of a CRAS. The agency refers to the tether securement point as a ''tether anchorage.'' For the CRS, this preamble

[1] 49 CFR 571.225, ''Child restraint anchorage systems.''

[2] The 2015 NPRM proposed changes to FMVSS No. 213; however, NHTSA recently amended FMVSS No. 213 and issued FMVSS No. 213b for plain language reasons relating to multiple compliance dates of the amendments (88 FR 84514). NHTSA decided the requirements would be easier to read and understand if the agency issued amendments becoming effective on December 5, 2024, for FMVSS No. 213 and December 5, 2026, for FMVSS No. 213b.

[3] NHTSA's 2011–2013 Priority Plan. Link: *www.regulations.gov/document/NHTSA-2009-0108-0032.*

[4] A full vehicle child restraint anchorage system has two lower anchorages and one tether anchorage in a designated seating position.

[5] Many in the child passenger safety community refer to the child restraint anchorage system as the ''LATCH'' system, an abbreviation of the phrase ''Lower Anchors and Tethers for Children.'' This term was developed by a group of manufacturers and retailers soon after the 1999 final rule (64 FR 10786) to educate consumers on the availability and use of the anchorage system and for marketing purposes. ''LATCH'' has historically been used in various field materials and by NHTSA to refer to the vehicle 3-point child restraint anchorage system. However, the term has also been used to refer to only the lower two anchorages of the system, or to refer to the connectors of the child restraint system that attach to the lower anchorages. Further, NHTSA understands many consumers identify the tether anchorage solely with the ''LATCH'' system, and thus mistakenly do not attach the CRS's tether strap when using the vehicle belt system to attach a child restraint. As such, NHTSA has chosen to avoid using the term ''LATCH'' in this document where possible to avoid ambiguity.

uses the following terms to refer to the various parts of a child restraint that connect to the CRAS, as appropriate: ''child restraint system connectors'' (or ''CRS connectors''), ''lower anchorage connector(s),'' ''tether anchorage connector,'' ''tether strap,'' and ''tether hook.''

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I. Executive Summary

a. Introduction

This final rule amends FMVSS No. 225 to improve the usability (ease-of-use) of the standardized CRASs required by the standard. Prior to FMVSS No. 225, CRSs were anchored to a vehicle seat solely by the seat belt. Because seat belts are primarily designed for passengers and not child restraints, incompatibilities existed between seat belts and CRSs. NHTSA issued FMVSS No. 225 in response to this problem to optimize the safety performance and ease of the correct use of child restraints through a dedicated CRAS. The standard aims to reduce the likelihood of an anchorage system's failure and increase the likelihood that CRSs are properly secured to achieve the CRS's safety benefits during motor vehicle crashes.[6]

The CRAS required by FMVSS No. 225 entails a 3-point system consisting of two lower anchorages and a tether anchorage, designed for attaching a CRS to a vehicle. Each lower anchorage consists of a 6-millimeter (mm) diameter straight rod, or ''bar,'' onto which a CRS connector can be attached.[7] The two lower anchorage bars are typically located at or near the seat bight (the area where a seat cushion intersects with the seatback) in a position where they will not be felt by seated adult occupants. The tether anchorage is a permanently installed vehicle system to which a CRS tether hook can be attached.[8]

CRASs meeting FMVSS No. 225 and child restraints meeting the associated requirements of FMVSS No. 213 have been successfully implemented in the fleet since the implementation of FMVSS No. 225. According to a 2006 study by Decina, consumers who use the CRAS generally like the system [9] and prefer using lower anchorages to attach child restraints to the vehicle over seat belt attachments. The study also found that CRASs help reduce the incorrect installation of child restraints (61 percent of CRSs installed with CRAS were securely installed compared to 40–46 percent of CRSs that were securely installed using seat belts).[10] However, the study found many consumers do not use CRASs because they do not know enough about the systems.[11]

Gathered data also indicates that many consumers misuse the CRAS or find aspects of it difficult to use. Specifically, in 2007 NHTSA held a public meeting on CRAS to see how the systems could be improved.[12] Attendees repeatedly stated that lower anchorages were often embedded deep into the seat bight, making it difficult for consumers to reach the lower anchorages and attach the lower anchorage connectors. Attendees also indicated that it was difficult to attach lower anchorage connectors to the lower anchorages because of surrounding stiff cushions, stiff fabric/leather, or the proximity of seat belt buckles. In response to comments received at the public meeting NHTSA studied possible ways to improve the usability of CRASs.[13] NHTSA used the information obtained from these studies to assist in responding to the 2012 Congressional mandate set forth in section 31502(b)(1) of MAP–21 in 2012, publishing an NPRM on January 23, 2015, to commence rulemaking to improve the ease-of-use of child restraint anchorage systems.[14]

b. Summary of the Final Rule

This final rule adopts most, but not all, of the proposals in the NPRM to improve CRAS ease-of-use. This final rule also adjusts several provisions in response to comments received on the NPRM.

1. This final rule amends FMVSS No. 225 to enhance requirements for the usability of CRASs. The final rule's requirements are based in part on findings from the University of Michigan Transportation Research Institute (UMTRI) about characteristics of the vehicle seat that enhance the usability of CRASs (''LATCH Usability study'').[15] This final rule adopts a ''clearance angle'' for each lower anchorage of at least 54 degrees (clearance angle relates to the clearance around a lower anchorage from interfering parts that can make it difficult to maneuver the CRS lower anchorage connector) and an ''anchorage depth'' limit (location of the lower anchorage within the seat bight)

[6] 49 CFR 571.225, S1.

[7] When NHTSA issued FMVSS No. 225, the agency also amended FMVSS No. 213 to require child restraint systems to have the CRS connectors permanently attached to each child restraint. In the case of rear-facing child restraints with detachable bases, only the base is required to have the components.

[8] FMVSS No. 225 requires vehicles with three or more forward-facing designated rear seating positions to be equipped with child restraint anchorage systems at not fewer than two forward-facing designated rear seating positions and a tether anchorage at an additional designated rear seating position. If the vehicle has fewer than three forward-facing rear designated seating positions, fewer child restraint anchorage systems are required.

[9] Decina, L., et al., ''Child Restraint Use Survey: LATCH Use and Misuse,'' December 2006, (''Decina study''), DOT HS 810 679, Docket No. NHTSA–2006–26735. The Decina study is summarized in Appendix A to the NPRM preamble.

[10] *Id.*

[11] *Id.*

[12] Docket No. NHTSA–07–26833. A summary of the public meeting can be found in Appendix B to the NPRM preamble.

[13] NHTSA included plans to address the CRAS usability concerns raised at the 2007 LATCH public meeting in its Vehicle Safety and Fuel Economy Rulemaking and Research Priority Plan (2011–2013). Docket No. NHTSA–2009–0108–0032.

[14] Further background on the development of the NPRM can be found in the NPRM preamble. NHTSA discusses its reasons for using the UMTRI LATCH Usability study, *infra,* in section III of the NPRM (80 FR 3748–3753).

[15] Klinich et al., *supra.* Link: *http://deepblue.lib.umich.edu/handle/2027.42/90856.* The report was sponsored by the Insurance Institute for Highway Safety (IIHS) for developing IIHS's rating of the usability of the child restraint anchorage systems in various vehicles. *See* IIHS Status Report: Vol. 47 No. 3, April 12, 2012.

of less than 25 millimeters (mm). Although the 2015 NPRM included an ''attachment force'' limit, NHTSA has decided not to adopt an attachment force requirement in this final rule based on comments received and additional study by NHTSA. This final rule's clearance angle and anchorage depth limit requirements will substantially improve consumer ease in using the lower anchorages of CRASs.

2. This final rule modifies the hand-held tools used to measure clearance angle and anchorage depth proposed in the NPRM. Comments received stated that the proposed tools yielded inconsistent results and were hard to use. In response, NHTSA undertook several studies, discussed below in this preamble, to refine the proposed tools and validate their improved repeatability and reproducibility in measurements. This final rule adopts these improved test tools.

3. This final rule restricts tether anchorages from being placed under a vehicle seat or hidden under vehicle components other than a marked tether anchorage cover. The rule also restricts how close the tether anchorage can be from the child restraint, (a too-close tether anchorage can make it impossible to tighten the tether strap properly), but does not adopt the location requirements that were detailed in the NPRM. Some vehicle manufacturers stated that the proposed requirements were too restrictive, involved a procedure that was not executable in certain vehicles, or would result in costly redesign. The procedure adopted in this final rule is less restrictive than those proposed in the NPRM, is clear to execute, and in some cases affects the re-location of the tether by a shorter distance or not at all. NHTSA is also giving more lead time coupled with a 3-year phase-in of the requirements to lessen the burdens of redesigning vehicles and to reduce costs.

4. This final rule amends FMVSS No. 225 to make tether anchorages easier to use by standardizing the configuration of the anchorage such that it is ''a rigid bar of any cross-section shape.'' However, in response to comments, the rule allows vehicles with unique space limitations in the vehicle interior, such as buses, light trucks, and convertibles, to have flexible anchorages that can also be used as a tether strap routing device.

5. This final rule standardizes the markings that will indicate to consumers the location and presence of the lower anchorages and the tether anchorage. These new markings are based on improved anchorage marking designs developed by the International Standardization Organization (ISO). Specifically, this final rule amends FMVSS Nos. 225 and 213b to require, among other things, vehicles and CRSs to use a standardized symbol to more clearly identify vehicle anchorages and CRS components that attach to those anchorages. With these markings all consumers can easily look for the specific marks and ''match up'' the symbols on the vehicle to the symbols on the child restraint.

6. This final rule amends FMVSS Nos. 213b to require the top tether hook and attachment hardware on child restraint systems to be limited in length, as proposed in the NPRM.

This preamble discusses these amendments and others in detail below.

c. How This Final Rule Differs From the NPRM

Highlighted below are the main differences between the NPRM and this final rule. More minor changes (*e.g.,* how a tool is oriented during a test) are not highlighted here but are discussed in the sections relevant to the topic.

The final rule differs from the NPRM in the following ways:

- This final rule does not adopt the proposed requirement for maximum attachment force of 178 Newtons (N) (40 lbf) to the lower anchorages to improve ease-of-use. NHTSA worked to improve the repeatability of the attachment force tool and conducted a repeatability and reproducibility (R&R) study. Results showed that the force measurements were not repeatable or reproducible enough to be adopted because the force attachment tool measurements contain too much variance.
- This final rule fine-tunes the proposed Clearance Angle and Depth Tools to achieve greater R&R in measurements. The improvements to the tools address comments on variability and subjectivity of the measurements. The improved tools incorporate new or additional instrumentation or features to enable consistent and non-subjective measurements.
- This final rule specifies that the lower anchorage must be located 25 mm or less within the seat bight instead of the 20 mm within the seat bight proposed by the NPRM. This increase in depth measurement takes into consideration the manufacturing variability across vehicles of the same model.
- This final rule does not adopt the proposed requirement for 165 mm minimum distance of a tether anchorage from a reference point on a vehicle seat to provide enough clearance for tightening the tether strap. Instead, this final rule requires the tether anchorages for vehicle seats with no head restraint or with adjustable or removable head restraints to be located outside of a zone bounded by a 325 mm radius sphere centered at the R-point of the vehicle seat and truncated by a horizontal plane located 230 mm below the sphere's center. This change was made to address multiple concerns from commenters. For example, the new zone addresses the difficulty of defining the proposed reference point (SB) and uses an already defined reference point in the standard (R-point). This measurement also takes into consideration the seat's depth to account for the distance that is routed over the seat towards the CRS, addressing a concern raised by one commenter. The new measurement required by this final rule will result in fewer vehicle models requiring tether anchorage relocation. Additionally, for those vehicle models requiring the relocation of tether anchorages, the relocation distance will, in most cases, be reduced. The final rule does not require vehicle seats with fixed head restraints to comply with the minimum distance of a tether anchorage from the R-point, as such seats do not have any elements that would interfere with the installation and tightening of the tether. To reduce cost burdens on the vehicles that will need redesign, we have extended the lead time for manufacturers to comply by introducing a 3-year phase-in that will begin on the first September 1 that is three years after publication of the final rule.
- This final rule revises the proposed forward-most allowable tether anchorage zone under the seat from the ''plane parallel to the torso line passing through the rearmost point of the bottom of the seat'' to a ''vertical transverse plane 120 mm rearward of the seating reference point.'' Commenters stated that the proposed allowable tether anchorage zone based on the rearmost point of the bottom of the seat may not be objectively determined in some seat designs. Additionally, commenters stated that some current seat designs with easily accessible tether anchorages located slightly under the back of the seat may not be compliant with the proposed tether anchorage zone. This final rule's alternative measurement can be objectively determined for all seat designs, will allow tether anchorages that are on the seatback but still accessible, and will prevent tether anchorages that are deep under the seat.
- This final rule provides exceptions to the NPRM's originally proposed requirement that all tether anchorages be rigid bars. Tether anchorages will not

be required to be rigid bars for buses with a GVWR less than or equal to 4,536 kg (10,000 lb) and for vehicles with DSPs where the ''allowable tether zone'' in FMVSS No. 225 falls in an area that is only accessible by removing a seating component of the vehicle. These vehicles can be equipped with tether strap routing devices that can be used as tether anchorages. Commenters stated that flexible tether anchorages (that can also be used as routing devices) in vehicles such as pick-up trucks are easy to use for installing CRSs but would no longer be permitted under the proposed requirements for rigid tether anchorages. If only rigid bar tether anchorages are permitted, the allowable locations for these tether anchorages would be behind the seatback where folding the seat or moving the seat forward is necessary to access the tether anchorage. Such a seat design requires an iterative tensioning of the tether to install a CRS, which is more time-consuming and difficult. Therefore, the agency is continuing to allow flexible anchorages in vehicle that cannot locate the tether anchorage in the allowable zone.

- This final rule updates the tolerances and positioning of lower and tether anchorages markings to that proposed in response to comments received. This final rule increases the tolerances of the position of the markings from that proposed in the NPRM and makes some allowances on the position of the markings to accommodate a variety of vehicle designs.
- This final rule adopts a 3-year phase-in period to comply with the updated requirements in FMVS No. 225. The phase-in period starts on the first September 1 that is three years after the publication of the final rule. This additional lead time and phase-in period will reduce potential tooling costs by allowing manufacturers the opportunity to make required changes to subject vehicles during their regular design update cycles.

d. Rulemaking Goals

The requirements of this final rule, aimed at increasing consumer use of CRASs for the installation of CRSs, will make the CRASs more conspicuous and easy to use.[16]

If CRASs becomes easier to use correctly, more consumers will achieve a tight fit of the CRS in the vehicle, resulting in reduced child head and torso excursions in motor vehicle crashes, and thus fewer child head and torso injuries from crashes. The goal of this rulemaking is supported by studies showing that many consumers are not aware of or do not fully understand the CRASs available in their vehicle. Specifically, the 2006 Decina study found that many consumers did not know about CRASs, that CRASs were available in their vehicle, the importance of using CRASs to install CRSs, or how to properly use CRASs. The Decina study also found that users attempting to use CRASs generally liked the systems, and that drivers with experience attaching a CRS using a CRAS strongly preferred using a CRAS's lower anchorages over seat belts. Moreover, the study found consumers were more likely to install a CRS correctly using a CRAS than a seat belt. Finally, the LATCH Usability study found that test subjects who correctly used the lower anchorage hardware were 3.3 times more likely to achieve a tight CRS installation than subjects who made errors using the hardware.

e. NHTSA's Determination of MAP–21 Requirements and Considerations

This final rule satisfies subtitle E, Section 31502 of the ''Moving Ahead for Progress in the 21st Century Act'' (MAP–21). Section 31502(a) requires NHTSA (by delegation of authority 49 U.S.C. 30111) to initiate a rulemaking proceeding to improve the ease-of-use for lower anchorages and tether anchorages in all rear designated seating positions if such anchorages and tether anchorages are feasible. Section 31502(b)(1) of MAP–21 states that, subject to exceptions, NHTSA (by delegation) must issue a final rule. An exception is for an amendment to Standard No. 225 which ''does not meet the requirements and considerations set forth in subsections (a) and (b) of section 30111 of title 49, United States Code [the National Traffic and Motor Vehicle Safety Act (Vehicle Safety Act)].'' As discussed below, NHTSA has made such a determination regarding the final rule amendments to FMVSS No. 225 to improve the ease-of-use of the CRAS.

The provision at 49 U.S.C. 30111(a) of the Safety Act authorizes the Secretary (NHTSA, by delegation) to prescribe Federal motor vehicle safety standards that are practicable, meet the need for motor vehicle safety, and are stated in objective terms. ''Motor vehicle safety'' is defined in the Safety Act as ''the performance of a motor vehicle or motor vehicle equipment in a way that protects the public against unreasonable risk of accidents occurring because of the design, construction, or performance of a motor vehicle, and against unreasonable risk of death or injury in an accident, and includes nonoperational safety of a motor vehicle.'' [17] This final rule meets the need for motor vehicle safety because it would increase the likelihood that CRASs and CRSs will be correctly used, thereby reducing the risk of injury to restrained children in motor vehicle crashes. This final rule improves the correct use of CRASs and CRSs by requiring the lower anchorages and tether anchorage of the CRAS to be more accessible, easy to use, and clearly labeled so that consumers can easily identify and use them. This final rule is practicable because a number of vehicle and child restraint models already meet the requirements of the final rule. NHTSA is also providing a substantial lead time to meet the requirements. Some vehicle seat designs will change pursuant to the rule, but the redesigns would involve relatively straightforward modifications to the existing vehicle materials (*i.e.,* the seat cushion); most vehicles will not have to change the vehicle structure. This final rule is objective because the requirements are stated in unambiguous terms and assessed using tools and procedures with demonstrated R&R.

49 U.S.C. 30111(b) specifies that, when prescribing Federal motor vehicle safety standards, the Secretary (NHTSA, by delegation) must, among other things, consider all relevant, available motor vehicle safety information, consider whether a standard is reasonable, practicable, and appropriate for the types of motor vehicles or motor vehicle equipment for which it is prescribed, and consider the extent to which the standard will further the statutory purpose of reducing traffic crashes and associated deaths and injuries. NHTSA has determined that this final rule is reasonable, practicable, and appropriate for the types of motor vehicles and child restraint systems for which it is prescribed. This final rule accounts for challenges that buses and light trucks could have in meeting the proposed requirement that all tether anchorages be rigid bars located in a particular zone. Among other things, the rule permits these vehicles to have tether strap routing devices that can be used as the tether anchorage if the rigid bar is not feasible.

NHTSA considered existing industry standards and conducted extensive research prior to the finalization of this

[16] NHTSA designed FMVSS No. 213 and No. 225 to require each applicable child restraint to be able to attach to a vehicle seat by way of the CRAS, and additionally by way of the seat belt (continuing what was done prior to the standard, so that child restraints could continue to be attached using the seat belt, which is at every designated seating position in a vehicle).

[17] 49 U.S.C. 30102(a).

final rule to improve the tools and test procedures in existing industry standards to ensure objectivity of the ease-of-use assessments. NHTSA's assessments indicate that most vehicle models and child restraints already comply with the requirements of the final rule. For products that do not, the final rule provides ample lead time for modifications to be implemented with little to no cost.

f. Estimated Costs and Benefits

The agency estimates that the adopted requirements for improved usability of CRASs would not result in any increase in material cost but would entail some redesign of vehicle seat features. In response to the comments received, NHTSA is providing a 3-year phase-in period to comply with the updated FMVSS No. 225 requirements. The phase-in period starts on the first September 1 that is three years after the publication of the final rule. We believe this approach would respond to commenters' concerns and provide sufficient time for vehicle manufacturers to accommodate any redesign of the vehicle seat and rear shelf structures to meet this final rule in their normal course of manufacture without a cost increase.

NHTSA estimates the cost of ISO markings for a set of lower anchorages to be $0.07 and that for the tether anchorage to be $0.03. The total incremental cost of equipping all CRASs with appropriate ISO markings is about $760,000. The final rule also requires similar ISO markings on child restraint anchorage connectors, for which the agency estimates an incremental cost of $970,000. The cost of changing the written instructions accompanying the vehicle or the CRS to explain the ISO markings is expected to be negligible (<<$0.01). Therefore, the total cost of the proposed rule is estimated to be $1.73 million.

These new usability requirements will assist in improving correct (tight) installation and increase tether use. If there were a 5 percent increase in correct installation using the lower anchors and a 5 percent increase in tether use, the agency estimates that the proposed requirements would save approximately 3 lives and prevent 6 moderate to higher severity injuries per year.

II. Statutory Authority

This final rule is issued under the Safety Act [18] (49 U.S.C. 30101 *et seq.*) and MAP–21.

Under the Safety Act, the Secretary of Transportation [19] is responsible for prescribing motor vehicle safety standards that are practicable, meet the need for motor vehicle safety, and are stated in objective terms.[20] ''Motor vehicle safety'' is defined in the Safety Act as ''the performance of a motor vehicle or motor vehicle equipment in a way that protects the public against unreasonable risk of accidents occurring because of the design, construction, or performance of a motor vehicle, and against unreasonable risk of death or injury in an accident, and includes nonoperational safety of a motor vehicle.'' [21] ''Motor vehicle safety standard'' means a minimum performance standard for motor vehicles or motor vehicle equipment.[22] When prescribing such standards, the Secretary must consider all relevant, available motor vehicle safety information, and consider whether a standard is reasonable, practicable, and appropriate for the types of motor vehicles or motor vehicle equipment for which it is prescribed.[23] The Secretary must also consider the extent to which the standard will further the statutory purpose of reducing traffic crashes and associated deaths and injuries.[24]

MAP–21

MAP–21 (Pub. L. 112–141) incorporates Subtitle E, ''Child Safety Standards.'' Subtitle E, section 31502(a), requires that not later than 1 year after the date of enactment of the Act, the Secretary (NHTSA, by delegation) shall initiate a rulemaking proceeding to amend FMVSS No. 225 ''to improve the ease-of-use for lower anchorages and tethers in all rear seat seating positions if such anchorages and tethers are feasible.'' NHTSA published the NPRM preceding this final rule on January 23, 2015. Section 31502(b)(1) of MAP–21 states that, subject to exceptions, the Secretary must issue a final rule not later than 3 years after the date of enactment of MAP–21. An exception is for an amendment to Standard No. 225 which ''does not meet the requirements and considerations set forth in subsections (a) and (b) of section 30111 of title 49, United States Code [the National Traffic and Motor Vehicle Safety Act (Safety Act)].'' [25]

NHTSA interprets section 31502(a) as directing DOT to initiate rulemaking to improve the ease-of-use of lower anchorages and tether anchorages currently required by FMVSS No. 225 if improved anchorages are feasible.[26] This final rule satisfies the mandate by adopting requirements that will improve the ease with which consumers can access and use the anchorages and improve the visibility of the anchorages so that consumers can more easily identify them as parts of a CRAS.

NHTSA carefully considered the potential merits of requiring additional CRASs in vehicles, with the NPRM requesting comment on whether additional lower anchorages and tether anchorages should be required in vehicles. Manufacturers commented that it is difficult to have additional CRAS systems due to spacing and complex designs that may increase misuse of the lower anchorages. Following careful consideration and review of comments, NHTSA has determined the available data does not support a safety need to require additional CRASs or tether anchorages in vehicles already covered under FMVSS No. 225.

The NPRM also requested comment on the merits and feasibility of installing tether anchorages and lower anchorages in vehicles excluded from such requirements by the issuance of FMVSS No. 225 in 1999. This final rule removes the current exclusion from tether anchorages for convertible vehicles [27] and vehicles described in FMVSS No. 225 S5(e) from having to provide lower anchorages and a tether anchorage in rear designated seating positions. This decision was made based on the agency's determination that installing the tether and lower anchorages in these previously excluded vehicles is practicable [28] and, given data showing the benefits of tether anchorages and CRASs, will meet the need for safety. These topics are discussed in greater detail below.

Section 31502 gives NHTSA no discretion in issuing a final rule if a rule would meet the conditions set forth in MAP–21. As discussed above, NHTSA has determined that amending FMVSS No. 225 as set forth in this final rule meets the requirements and considerations established in subsections (a) and (b) of 49 U.S.C 30111 and are feasible. Accordingly,

[18] National Traffic and Motor Vehicle Safety Act (Safety Act).

[19] The responsibility for promulgation of Federal motor vehicle safety standards is delegated to NHTSA. 49 CFR 1.95.

[20] 49 U.S.C. 30111(a).

[21] 49 U.S.C. 30102(a)(8).

[22] 49 U.S.C. 30102(a)(9).

[23] 49 U.S.C. 30111(b).

[24] *Id.*

[25] *See* 49 U.S.C. 31502(b)(2).

[26] *See* 80 FR 3747 Section II. Statutory Mandate.

[27] S5(a) of FMVSS No. 225.

[28] There are vehicles that have solved the challenges of providing lower anchorages and tether anchorages, proving that solutions are feasible.

NHTSA is issuing this final rule as mandated by MAP–21.

III. Summary of the NPRM

The NPRM proposed to reduce the physical difficulties associated with attaching a child restraint to the lower anchorages and to the tether anchorage, and to improve how easily a consumer can identify the anchorages and match them up with parts on a child restraint system. Regarding the physicality of using the vehicle's CRAS, the proposed changes to FMVSS No. 225 were based on the findings in UMTRI's LATCH Usability study, *supra,* about characteristics of the vehicle seat that enhance the usability of CRASs. NHTSA proposed the limits on the clearance angle, attachment force, and the depth of the anchorage in the seat bight to address the ease-of-use problems described in the Decina study, *supra,* and expressed by various attendees to the 2007 public meeting. The NPRM's proposals are further summarized below.

Ease of Using Lower Anchorages

Although FMVSS No. 225's current requirements for the location of lower anchorage bars near the seat bight intend for the bars to be accessible, some consumers find it difficult to use the bars. NHTSA proposed new requirements for the bars to improve ease-of-use: a minimum ''clearance angle'' of 54 degrees (clearance angle relates to the clearance around a lower anchorage from interfering parts that can make it difficult to maneuver the CRS's lower anchorage connector), a maximum ''attachment force'' of 178 N (40 lbf), and an ''anchorage depth'' of less than 20 millimeters (mm)). These are the ease-of-use specifications the UMTRI LATCH Usability study found to correlate with correct child restraint installation by test subjects.

In accordance with the LATCH Usability study, NHTSA proposed the use of three new tools: one to measure clearance angle, another to measure attachment force, and a third to determine anchorage depth. Clearance angle would be measured by a tool based on a Society of Automotive Engineers (SAE) draft J2893 recommended practice that attaches to the lower anchorages. Attachment force would be measured by a force gauge. Anchorage depth would be measured by a simple tool, similar to one UMTRI developed, with a hook-type CRS connector marked every 20 mm. The NPRM also proposed to incorporate by reference drawing packages into FMVSS No. 225.

Ease of Using Tether Anchorages

FMVSS No. 225 currently requires tether anchorages to be located in a specified zone and to be accessible without the need for any tools other than a screwdriver or coin. To improve the usability of the tether anchorage, NHTSA proposed the following requirements to make it easier for consumers to recognize and access the anchorage.

- The NPRM proposed to reduce the zone in which a tether anchorage must be located, to prevent tether anchorages from being placed deep under a vehicle seat.
- The tether anchorages would have to be accessible without the need for any tools and without folding the seatback or removing carpet or other vehicle components. The tether anchorage could be covered with a cap, flap, or cover, provided that the cap, flap, or cover is specifically designed to be opened, moved aside, or to otherwise give access to the anchorage without the use of any tools and is labeled with a specific symbol indicting the presence of the tether anchorage underneath.
- Some tether anchorages are too close to a structure, such as a head restraint, to allow tightening of the tether strap. NHTSA proposed to specify a minimum 165 mm (6.5 in) distance from a specified reference point on the vehicle seat to the tether anchorage so that adequate clearance will be provided for tightening of the tether strap.
- Currently, there are some tether anchorages made from flexible webbing. NHTSA proposed to require that the tether anchorage be a standardized rigid bar so consumers could more easily recognize and find it.
- NHTSA proposed to limit the length of the CRS tether hardware assembly (which consists of a tether hook and hardware to tighten and loosen the tether strap) to 165 mm (6.5 in) so that the tightening mechanism can be easily used in the clearance space around a tether anchorage.

Enhanced Ability To Identify Anchorages

In relation to consumers' seeing or recognizing the anchorages, FMVSS No. 225 currently requires the lower anchorage bars to be visible, or that the vehicle seat back be marked showing the location of the bars. To improve consumers' ability to see, recognize, and use lower anchorages, NHTSA proposed to require that motor vehicles be marked with a standardized ISO-developed marking near the location of each lower anchorage bar even when the lower anchorage is visible. Similarly, tether anchorages would be marked with the ISO-developed marking. To complement these markings, NHTSA proposed that child restraints bear the same ISO marking on the lower anchorage connectors on the child restraint system and on the tether hook or tether strap, so consumers could be taught to match up the symbols when they attach a CRS.[29]

IV. High Level Summary of the Comments Received

NHTSA received submissions from 30 entities. The commenters fell into the following general categories: vehicle manufacturers or associations (the Alliance of Automobile Manufacturers (Alliance), Association of Global Automakers (Global),[30] Ford Motor Company (Ford), General Motors Company (GM), American Honda Motor Co., Inc. (Honda), Fiat Chrysler Automobiles U.S. (Chrysler),[31] Toyota Motor North America (Toyota), Porsche Cars North America, Inc. (Porsche), and Hyundai Motor Company (Hyundai)); child restraint manufacturers (the Juvenile Products Manufacturers Association (JPMA), Britax Child Safety, Inc. (Britax), Dorel Juvenile Group (Dorel), and Graco Children's Products, Inc. (Graco)); suppliers (Motor and Equipment Manufacturers Association (MEMA), and HSM Transportation Solutions, Inc. (HSM)); auto dealers (National Automobile Dealers Association (NADA)); forensics experts (ARCCA); consumer advocacy groups (Advocates for Highway and Auto Safety (Advocates), Safe Kids Worldwide (Safe Kids), Safe Ride News (Safe Ride News); research-associated organizations (University of Michigan Transportation Research Institute (UMTRI), Insurance Institute for Highway Safety (IIHS), MGA Research Corporation (MGA), Consumer Union [32]); and other (including private individuals).

There was almost unanimous agreement for improving the ease-of-use of CRASs. However, commenters varied in their support for specific requirements in the proposal. Many vehicle manufacturers expressed concern about the extent of changes needed to meet some of the

[29] The NPRM also proposed to require vehicle and child restraint manufacturers to provide written information (*e.g.,* in owners' manuals) explaining the meaning of the ISO markings.

[30] The Alliance and Global later merged and became the Auto Innovators. This document refers to these commenters in the name in which the comment was submitted.

[31] Fiat Chrysler Automobiles U.S. is now Stellantis North America.

[32] Consumers Union is the public policy and advocacy division of Consumer Reports.

requirements. Specifically, the manufacturers expressed concerns over extensive redesign to relocate tether anchorages, costs of relocating the tether anchorage, and challenges of meeting some of the lower anchorage requirements given the involvement of soft seating surfaces. Some manufacturers stated there was no need to specify all three requirements (clearance angle, attachment force, and anchorage depth). Suppliers urged NHTSA to provide more flexibility in marking vehicle seats to identify lower anchorage locations so suppliers could avoid extensive redesigns that would impose costs on suppliers and vehicle manufacturers. Several vehicle manufacturers stated that the clearance angle, attachment force, and anchorage depth test tools did not produce repeatable or reproducible measurements, stating the proposed test procedures were ambiguous and could not be followed. Vehicle manufacturers generally objected to the proposed 3-year lead time as insufficient to account for necessary changes. Many vehicle manufacturers asked for a phase-in of the requirements.

Commenters split on the issue of removing certain vehicle exemptions in FMVSS No. 225, such as the exclusion of convertible vehicles from the requirement to provide tether anchorages (S5(a)), or vehicles described in S5(e) of the standard from having any CRAS. A vehicle manufacturers' association and vehicle manufacturers responding to the issue were generally opposed to removing the exemptions. Consumer advocates and research organizations strongly supported removing the exemptions.

Many consumer advocates and research groups supported the NPRM but contended the proposal should go further to improve the ease-of-use of the anchorage systems. Consumer advocates and individuals described numerous problems seen in the field that they believed should be addressed. Overall, child restraint manufacturers and private individuals supported the proposal.

Many commenters responded to NHTSA's questions posed in Section X of the NPRM (80 FR 3764). Included in this section were questions about whether there were safety concerns about using a ''simulated'' CRAS in the rear center seating position.[33] Most commenters concurred they did not see safety issues raised using simulated CRASs in rear center seating positions, provided the child restraint and vehicle manufacturer at issue supported such use. NHTSA also asked whether its education materials should recommend that tethers should be used for all children regardless of the child's weight in the child restraint, based on data indicating inherent benefits stemming from the use of a tether.[34] Most commenters on the issue supported the agency's recommendation that tethers should be used by all children regardless of weight, but one commenter (the Alliance) was opposed due to the current strength requirements in FMVSS No. 225, which limit the forces a tether anchorage can hold.

Many commenters provided input on issues that were outside of the scope of the rulemaking. NHTSA may consider these ideas for possible future updates to FMVSS No. 213 and/or No. 225, but generally will not further address comments outside the scope of the rulemaking in this document.

V. Improving the Ease of Using Lower Anchorages

a. Attaching to the Lower Anchorages

The NPRM proposed ease-of-use requirements to ensure that vehicle manufacturers produce lower anchorages that: (a) have sufficient clearance around each lower anchorage for consumers to maneuver the CRS connector to attach to the lower anchorage (''clearance angle'' of 54 degrees or more); (b) are located such that the CRS connector can be attached to the bar without applying excessive force (''attachment force'' 178 N (40 pounds (lbf)) or less); and, (c) are not too deep within the seat bight so they are easily accessible (''anchorage depth'' twenty millimeters (mm) or less from the outer surface of the seat bight).

General Comments

Commenters varied in their views about the proposed clearance angle, attachment force and anchorage depth requirements. Consumer advocates expressed general support for the proposed lower anchorage usability requirements. Advocates for Highway and Auto Safety (Advocates) stated that the strengthening of FMVSS No. 225 through the proposed revisions will likely result in more children being properly restrained. Advocates concurred with the agency's view that improvement in ease-of-use of the CRASs will increase use of CRSs and proper child restraint system installation, which will in turn improve child safety. Consumers Union supported the NPRM because, in their opinion, CRASs provide an easier and more secure installation than seat belts.

IIHS strongly supported the NPRM, stating that IIHS confirmed UMTRI's findings in the real world using data from Safe Kids' car seat checkpoints from records of more than 14,000 child restraint installations. IIHS found that anchor depths less than 4 cm, clearance angles greater than 54 degrees, and attachment forces less than 178 N (40 lbf) were associated not only with correct use, but also with use of the anchorage system. While the commenter suggested the attachment force tool could be improved, IIHS supported incorporating the proposed measures into FMVSS No. 225. IIHS stated the proposed thresholds are supported by real-world and laboratory data.

In contrast, many vehicle manufacturers expressed concerns about the proposed requirements for lower anchorages. They expressed concern about the extent of changes needed to meet some of the requirements and the difficulties in consistently meeting requirements involving measurements on soft materials like foam and cushions. The Alliance supported the goal of establishing ease-of-use measurements for the lower anchorages but did not agree with the proposed requirements and test methods. The Alliance commented that only an anchorage depth requirement is needed. It stated that the LATCH Usability study showed the measurement of attachment force and clearance angle serve as surrogates for anchorage accessibility. The commenter stated vehicles with anchorages deeper in the seat bight generally had a smaller clearance angle and higher attachment force in the study and that more visible anchorages had larger clearance angles and lower attachment forces, making the child restraint attachment step easier to accomplish.

The Alliance stated that, since the proposed requirements for anchorage location (anchorage depth) will expose the lower anchorages in the vehicle, it can be expected that the attachment forces will be lowered and the clearance angles will increase by design, making the attachment force measurement and clearance angle measurement unnecessary. Similarly, Fiat Chrysler

[33] A ''simulated'' child restraint anchorage system consists of the inboard lower anchorages of the CRAS in the two outboard seating positions and the tether anchorage in the center seat. NHTSA explained in the NPRM preamble that available data indicate that simulated CRASs appear crash-worthy and acceptable. Given these data, the agency sought comment on whether NHTSA should encourage or require CRS and vehicle manufacturers to include, in instruction manuals, statements that endorse the use of simulated CRASs in the rear center seating position to consumers who wish to place a CRS in that center position.

[34] That is, even if the tether or anchorage broke in a severe crash, the tethering would have attenuated some of the crash forces.

Automobiles U.S. (FCA) [35] stated that clearance angle, force, and anchorage depth are mutually inclusive and supported the Alliance's position that relocating anchorages further forward in the vehicle will generate similar results to the proposed requirements. FCA recommended removing the attachment force and clearance angle criteria.

Comments Specific to the Tools

The NPRM proposed to assess clearance angle, attachment force, and anchorage depth using a set of specialized tools based on the tools used in the UMTRI study. Prior to the NPRM, NHTSA evaluated the proposed procedures and tools in 10 vehicles, model years (MY) 2005–2013, and concluded that the procedures appear objective and repeatable.[36]

Notwithstanding the agency's data, several vehicle manufacturers raised concerns about the usability of the proposed test tools and questioned the repeatability and reproducibility (R&R) of test tools measurements and recommended more refinement of the tools.

Clearance Angle Tool (CAT)

Clearance angle relates to the open space around a lower anchorage, free from interfering seat components. Interfering components can make it difficult to maneuver and attach a CRS lower anchorage connector. A clearance angle requirement facilitates easier attachment of a CRS lower anchorage connector by ensuring surrounding components do not impede access to the anchorage.

NHTSA proposed a clearance angle measurement tool, illustrated in figure 1 in the NPRM, for this final rule. That clearance angle tool (CAT) includes a load cell with a handle to measure the applied vertical force on the tool and a potentiometer to measure the angle achieved with respect to the horizontal plane by the tool during the force application. In the proposed test procedure, the CAT is attached to a lower anchorage. A vertical force of 67 N (15 lbf) is applied to the tool. The angle the tool measures (with respect to the horizontal) when that force is applied is the ''clearance angle.'' The NPRM proposed to adopt a clearance angle requirement of not less than 54 degrees, as supported by the findings of the LATCH Usability study.

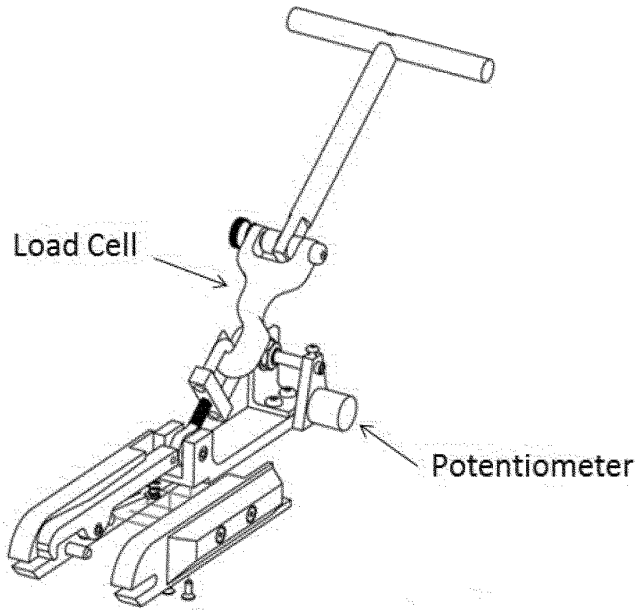


Figure 1. Proposed Clearance Angle Tool (CAT)

Some of the Alliance members commented on their experience with the SAE Prototype and UMTRI clearance angle test devices. The members stated they found those devices difficult to use and not sufficiently repeatable. GM and FCA commented that oscillations caused by the free-hanging weight attached to the rotary potentiometer resulted in non-repeatable measurements. GM recommended replacing the rotary potentiometers on the CAT with a digital inclinometer connected to a data acquisition system. FCA commented that without real-time readout of the vertical force applied, the operator will always overshoot/undershoot the specified vertical load. Similarly, GM recommended adding a means of indicating the force to the operator during the measurement process so that the operator is notified when 67 N (15 lbf) is achieved. GM and the Alliance recommended a small diameter cylindrical style load cell with a lower range of measurement. GM also stated that the multiple pivot points between the handle and the load cell and between the load cell and the main body should be reduced to a single pivot at attachment to the main body.

GM stated that, in some cases, it is difficult to apply the vertical force due to interference with the seatback. FCA commented that an operator will have difficulty maintaining 67 N (15 lbf) of vertical force even if there was a real time display of the vertical force. GM recommended that the handle pivot point to the main body on the tool be moved farther from the connection to the lower anchorage to allow more

[35] FCA changed its name in 2020 to Stellantis. This preamble refers to the commenter by its name on the comment, FCA.

[36] NHTSA Technical Report, ''Evaluation of LATCH Usability Procedure,'' Docket No. NHTSA–2014–0123–0005.

clearance between the load cell and the seatback. GM indicated that eliminating this interference should improve the repeatability of the process. GM added that the equivalent moment can be applied by specifying a lower force along with the increased moment arm.

Attachment Force Tool (AFT)

Vehicle manufacturers raised concerns that the attachment force tool did not provide repeatable or reproducible results. Ford suggested that NHTSA include in FMVSS No. 225 language that would permit an average of several trials (*i.e.,* five trials of each anchorage) as criteria for compliance. Ford and the Alliance stated that the repeatability of this test is very dependent on operator skill and experience and not adequately repeatable and reproducible when used by different operators in different labs.

The Alliance explained that many vehicle models feature lower anchorage designs that include either a cover or a slit in the seat cushion that allows access to the anchorage bar. Assuming that these types of design are not prohibited by the new proposed maximum attachment force requirement for lower anchorages, the Alliance recommended that the test be rerun if the test device becomes caught in the slit or cover.

GM commented that the AFT does not provide real-time feedback, making it difficult to ensure the operator performs the insertion force measurement at a consistent angle with the 0–45-degree range specified. GM noted that this would be particularly important if the trim interferes with insertion of the tool. GM added that the operators found the AFT angle difficult to control with the short T-handle (*see* figure 2) while trying not to touch the tool beyond the load cell. GM found that a digital inclinometer was helpful in observing the angle and improved its confidence in the force data being collected. GM recommended that the rotary potentiometer be replaced with a digital inclinometer including a real-time readout for the operator and a signal output for data acquisition. GM also suggested that the T-handle be replaced with a longer axial handle to improve control of the insertion angle and to avoid touching the tool along the load path.

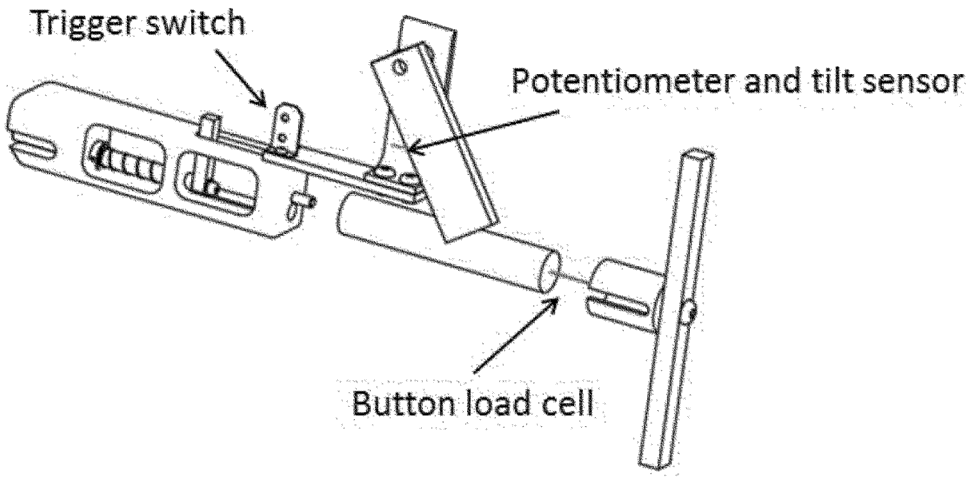


Figure 2. Proposed Attachment Force Tool (AFT)

GM commented that the AFT does not indicate to the operator that the switch used to detect full engagement of the tool on the anchorage bar has been activated. GM explained that this lack of an indication could result in a ''no switch closure'' event, and that the peak attachment force prior to bottoming out cannot be determined if this happened. GM added that if the AFT was not sufficiently perpendicular to the anchorage bar, it would be possible to mechanically bottom out the tool without closing the switch and that the perpendicular requirement is dependent on the distance the slide pin must travel before activating the switch. Additionally, GM stated that, depending on the lower anchorage style in the vehicle, particularly for non-visible anchorage bars, it can be difficult to determine perpendicularity.

GM requested that the current tool be revised to allow a larger tolerance to the range of perpendicularity, as a child restraint anchorage connector may be attached at a larger range of angles than the current tool design. GM suggested that this goal may be accomplished by lengthening the slide pin or increasing the thickness of the slide tab and that either solution will allow the slide tab to close the switch earlier during anchorage bar engagement and increase the perpendicularity tolerance. GM also recommended that an LED be included on the tool to indicate to the operator when the switch is closed.

GM also commented on the oscillations caused by the free-hanging weight attached to the rotary potentiometer. GM noted that, depending on the timing, the angle value at the time of switch closure could be very close to a maximum or a minimum of an oscillation. GM explained that in the example in figure 2 of its comment submission,[37] the oscillation is within the 0 to 45 degree force application range specified in the proposal; however, these oscillations can be eliminated by the utilization of a digital inclinometer. GM recommended that the rotary potentiometer be replaced with a digital inclinometer that includes a real-time readout for the operator and a signal output for data acquisition. GM added that the rotational freedom of motion of the AFT makes it difficult to control without touching the tool beyond the load cell and potentially altering the force measurement. GM also noted that the wiring to the load cell is susceptible to damage due to its location relative to

[37] NHTSA–2014–0123–0056.

the handle used to apply the force.[38] GM recommended that an in-line load cell with a threaded attachment between the main body and the handle be adopted to alleviate these issues.

Similarly, FCA commented that the potentiometer attached to the weight that is allowed to swing freely to capture the angle causes oscillations in the recorded angle, that at the point in time when the switch is triggered the attachment force increases drastically, the operator's rate of force application can influence the results, and that the AFT can interact with the seat cushion.

Global requested that lateral and vertical motions with the proposed tool be allowed prior to the application of the insertion force perpendicular to the center of the anchorage bar to represent typical actions taken by the consumer when attaching a child restraint to the lower anchorages.

IIHS stated that the agency's proposed changes to the AFT should improve repeatability of measurements over the tools used in the original IIHS/UMTRI research. IIHS provided the following two concerns:

1. IIHS and UMTRI stated the recorded attachment force should be the peak force from initial engagement with the seat cushion until full engagement of the tool on the lower anchorage. IIHS added that for some vehicles the peak force occurs as the tool is inserted between the cushions. IIHS stated such a peak force will not be captured when following the proposed protocol because the AFT records the force only at full engagement with the lower anchorage.

2. IIHS explained that the proposed changes to the tool do not address the off-axis vertical force required to align the tool with the lower anchorage.[39] IIHS noted this vertical force was not measured in NHTSA's evaluation. Instead, the force was assigned subjective ratings, making it difficult to standardize the measurement procedure and limiting R&R. IIHS noted it had developed a lower anchorage attachment force tool[40] that eliminates the need for additional vertical or lateral forces. This IIHS-developed tool replaces the slide pin, slide tab, and spring assembly with a square cross-section guide rod with a convex notch that prepositions the tool, aligning it with the lower anchorage bar before the force is applied. IIHS added that the new tool replaces the original depth gauge, as the depth scale is inscribed on the IIHS revised tool.[41] IIHS encouraged NHTSA to make further refinements to the attachment force tool to remove the need for off-axis forces to properly align with the lower anchorage bar.

Hyundai commented that the proposed AFT did not represent the hardware currently used in CRSs in the market. Hyundai stated it observed 100 percent of forward facing/convertible child seats sold at a retail store it visited are either the Safeguard clip system[42] or a simple hook. Hyundai noted the AFT has an exaggerated flat front face that requires more effort to insert into the seat bight for attachment. Hyundai also noted the attachment slot of the tool is not tapered, potentially leading to false readings if not properly engaged with the attachment bar. Hyundai performed a comparison evaluation with the proposed tool and found that the force was reduced by 20–50 percent when using a Safeguard attachment clip common in the industry. Hyundai pointed out that CRS manufacturers have already found a solution for increasing ease-of-use in attaching hardware by only using the Safeguard clip system connectors or a simple hook system.

Anchorage Depth Tool (ADT)

Anchorage depth refers to how deeply the lower anchorages are embedded in the vehicle seat (usually in the seat bight or seatback). The LATCH Usability study found that an anchorage depth of less than 20 mm within the seat bight is associated with a significantly higher rate of correct lower anchorage use than anchorage depths of 20 mm or more. NHTSA proposed a requirement for each lower anchorage to have an anchorage depth of less than 20 mm, as measured by a specially designed lower anchorage depth tool (ADT). The proposed ADT incorporates a hook-type CRS connector (*see* figure 3). The 20 mm distance is marked on the tool. In a compliance test, the tool would be attached to a lower anchorage. The NPRM proposed that the 20 mm mark would have to be visible from a vertical longitudinal plane passing through the center of the bar, along a line making an upward 30-degree angle with a horizontal plane, without the technician manipulating the seat cushions in any way.

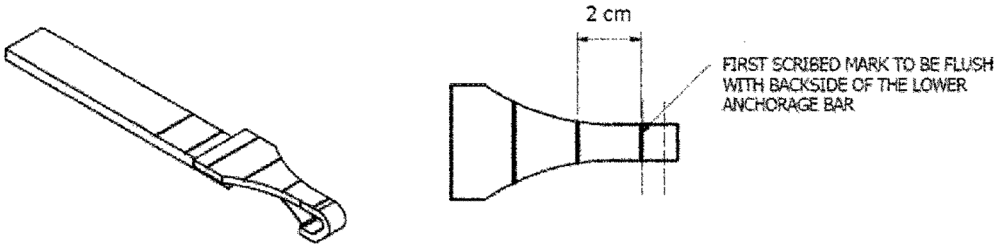


Figure 3. Proposed Anchorage Depth Tool (ADT) (left) and Top View (right)

The Alliance explained that the current requirements for FMVSS No. 225 are based on the visibility of the lower anchorages around the soft trim and that the current FMVSS No. 225 does not place the vehicle development process at risk as the standard gives manufacturers the option to certify the vehicles by adding seat cover markings if the lower anchorage is not visible. The Alliance stated anchorage depth in the current regulation is defined relative to a reference point, ''Z'' on the child restraint fixture (CRF), and the rearward-most location is defined in

[38] Figure 3 of GM's comments can be found in Docket No. NHTSA–2014–0123–0056.

[39] Evaluation of LATCH Usability Procedure, Louden et al., 2014.

[40] IIHS provided drawings of the new tool and a more detailed description of its use in its comments. *See www.regulations.gov/comment/NHTSA-2014-0123-0020.*

[41] Cicchino JB, Jermakian JS. ''Vehicle characteristics associated with LATCH use and correct use in real-world child restraint installations.'' Journal of Safety Research. 2015 June. *www.iihs.org/topics/bibliography/ref/2068.*

[42] Safeguard is a brand that produces push-on-type lower anchorage connectors.

Section 9.2.2(a) as: ''Not more than 70 mm behind the corresponding point Z of the CRF, measured parallel to the bottom surface of the CRF and in a vertical longitudinal plane, while the CRF is pressed against the seatback by the rearward application of a horizontal force of 100 N at point A on the CRF'' and that section S9.2.2(b) requires that the anchorage be located ''Not less than 120 mm behind the vehicle seating reference point.'' The Alliance explained that these two requirements ''in essence'' create the fore/aft ''zone'' for anchorage placement with respect to the seating reference point and the positioned CRF. The Alliance stated that during initial design of a vehicle, a virtual CRF is placed on the nominal seat to define the maximum anchorage depth and that this process locates the anchorages relative to defined hard points and ensures that the final anchorage location will be compliant to the regulation. The Alliance added that the application force of 100 N allows for the variation of foam and trim in a production vehicle.

Difficulty Meeting the Current Lower Anchorage Location Requirements and the Proposed Anchorage Depth Requirement

The Alliance explained that with certain current vehicle and seat designs, it is challenging to balance the maximum distance that the anchorage can be from the Z-point on the CRF with the 120-mm minimum distance the anchorage can be from the seating reference point (SgRP). The Alliance added that it may be difficult to meet the proposed lower anchorage depth requirements without violating the minimum distance the anchorage can be located from SgRP (S9.2.2(b)). The Alliance questioned the agency's conclusion that because the proposed anchorage depth specifies an anchorage must be less than 20 mm deep into the seat bight, lower anchorages will be able to meet the proposed requirement without conflicting with S9.2.2(b). The Alliance disagreed with NHTSA's conclusion, stating that (1) it does not consider the trim surface variation described above, and (2) it assumes all lower anchorages are located at the bight line, which is often not the case in vehicles with high bight lines.

Difficulties in the Design Process for Ensuring Compliance With the Proposed Lower Anchorage Requirements

The Alliance and FCA explained that the seat development process begins with virtual modeling tools used to establish the Vehicle Occupant Package (VOP) ''hard points,'' such as h-point, torso angle, seat belt anchorage locations, seat structure dimensions, etc., as well as the location of the lower anchorages. The Alliance and FCA added that these VOP ''hard points'' are established to ensure the final vehicle package will conform to all regulatory requirements while supporting customer-driven objectives such as comfort, seat adjustment forces, etc., for the seat design.

The Alliance and FCA added that the production seat contour cannot be developed exclusively in the virtual design space and that design models cannot adequately capture the complex interaction of foam and trim tension, folding actuation clearance, and comfort requirements. The Alliance noted that in the typical vehicle development process, the seat trim outline (STO) begins in the CAD design space and then matures through several phases of physical properties to allow incremental evaluation of the VOP dimensions, occupant comfort, seat folding/adjusting efforts, and overall appearance.

FCA explained that early seat development properties are built using skived foam (a foam cut from a solid block of foam) and that while these properties allow early evaluations of customer driven factors such as seat comfort, they are only directionally representative of final seat designs. FCA added that this is because skived foam does not have the same force/displacement properties of production cast foam and that production foam is produced using a molding process that results in a ''skin'' at the surface of the foam and a variable density and stiffness that cannot be mimicked by skived foam (which has a constant density and stiffness). As a result, FCA explained it cannot accurately predict child seat installation efforts with the accuracy and confidence necessary for regulatory compliance.

The Alliance and FCA stated that the virtual seat design process lacks the material properties necessary to predict lower anchorage attachment force with the accuracy necessary to guarantee regulatory compliance and that vehicle manufacturers will run the risk of late changes to the product design that will significantly increase design, manufacturing, and testing costs.

The Alliance and FCA recommended that the agency investigate alternatives to those in the proposal, including dimensional reference from a CRF, to determine a more objective method of measurement that will accomplish the associated ''ease-of-use'' goal. FCA stated this approach will accomplish the goal of relocating anchorages closer to the seat bight, while still using proven design and compliance measurement processes.

FCA stated that while it supports the overall goal of increasing the ''ease-of-use'' of child restraint systems for caregivers, the proposed requirements and test methods are too dependent on ''soft'' seat features like trim and foam. Similarly, the Alliance stated that the proposed method is overly sensitive to foam stiffness and the production variability between trim surface and the lower anchorages could exceed 20 mm.

Ford stated it does not agree that seat design changes needed to meet the proposed lower anchorage requirements can be accomplished through steps such as cutting larger open areas in the seat foam surrounding the lower anchorage bars, as stated by NHTSA in the NPRM. Ford explained that the manufacturing process for seat cushions doesn't typically involve secondary cutting operations. Ford also stated that design changes to meet the proposed requirements would require modifications to foam tooling. Ford explained these modifications could require inserts and separate compartments in the tool to locally revise the density of the foam and that any local voids in the cushion or seatback to provide clearance to anchorages would require a more labor-intensive process to sew trim covers to achieve acceptable appearance and craftsmanship. Ford also explained that since the system characteristics are evaluated after the seat is built, the design process will be iterative, and won't be fully understood until it fabricates the assessment tools and conducts evaluations of existing vehicles.

Ford stated that, at minimum, the proposed requirements would require seat cushion, back foam, and trim changes to locally modify the foam density in the area of the lower anchorages. Ford added that lower anchorage bars in some vehicles may require modification so that the anchorages extend further forward in-vehicle.

Subjectivity Reading Angle and ADT Angle During Measurement

FCA expressed concerns that the angle of the line of sight for measuring the lower anchorage depth using the ADT can vary due to the parallax effect and therefore the lower anchorage depth measurement is user-dependent and lacks objectivity. Similarly, GM explained that the ADT measurements are subjective in some cases, such as when overlapping trim opening is

present.[43] GM requested clarification of the procedure regarding trim covering or surrounding trim being displaced by the tool and the angle of the tool during determination of the depth measurement. The Alliance stated there were differences between the UMTRI LATCH Usability study and the NPRM ADT measurements. The Alliance noted that the UMTRI Study specified no tension on the hook, which implies that the ADT will lie on the seat cushion, while the Vehicle Research and Test Center (VRTC) study was kept approximately parallel with the seat cushion. The Alliance added that S9.2.2(a) did not specify any tension to be maintained in the ADT, so it is implied that the tool would lie on the seat cushion when making the measurement. GM recommended that the test procedure require that the tool be kept parallel to seat cushion when reading the depth measurement.

Repeatability

FCA expressed concern regarding the tool's R&R during two different ex parte meetings with NHTSA.[44] During the September 21, 2015, meeting, FCA presented two R&R studies showing the measurements with the force and clearance angle tools had poor repeatability and reproducibility. FCA recommended NHTSA conduct its own R&R study and harmonize tools with IIHS if possible. GM also presented results from a limited study of gauge repeatability with the proposed tools during a November 23, 2015, ex parte meeting.[45] GM explained that the gauge repeatability study showed that further refinement of the proposed tools was required to meet industry guidelines of repeatability.

b. Post-NPRM Research

After careful consideration of comments received in response to the NPRM, NHTSA carried out a study to assess whether and how the tools proposed in the NPRM could be modified. Specifically, some commenters expressed concerns about the R&R of the tools and the subjectivity of some measurements. Some commenters suggested improvements to the tools and the tools' instrumentation to have more repeatable measurements and better usability. Finally, some commenters also stated that NHTSA should harmonize or adopt the tools and procedures being used by the IIHS for consistency of evaluation on the lower anchorage attachments.[46]

During the course of the study, NHTSA reviewed IIHS's rating protocols and tools to consider any beneficial features provided by the tools. NHTSA proceeded to implement tool improvements to address the commenters concerns by updating the AFT and its instrumentation via an iterative process.[47] Specifically, NHTSA added features to the AFT, similar to the IIHS rating protocol,[48] by including a guide rod to guide the tool towards the anchorage. Other modifications included updating instrumentation to digitally record the angle during the test, adding an actuator allowing for a steady rate of force application, and adding a support leg to stabilize the tool and maintain the approach angle during the attachment force measurements. These modifications were expected to produce more consistent results by resolving the issue of aligning the tool with hidden anchorages, reducing the inconsistencies from off-axis loading and having more consistent readings with new instrumentation. The repeatability study results are discussed in greater detail in the GR&R Study portion of this section below.

For the updated CAT, NHTSA added a pulley bridge (with adjustable feet to make it level) to apply a 67 N (15 lbf) force vertically to remove the difficulty of applying the constant load manually. NHTSA also added digital instrumentation that allowed time-history data to be recorded. Further, NHTSA replaced the rotary potentiometer several commenters expressed concerns about with an analog position sensor to collect the angle data more reliably. To improve durability, the jaw of the tool was also reinforced with steel plates and the latch tooth was updated to be refabricated completely out of steel.

For the depth measurement[49] NHTSA modified the ADT through the addition of a sliding view bar to create a more consistent view angle and an additional depth gauge measurement device to provide a numerical value for the depth, rather than using color markings for the 20 mm depth reading.

GR&R Study

Following its initial study and tool modifications, NHTSA considered comments expressing concerns over tool repeatability and reproducibility. In response to comments that NHTSA should use the industry's standard gauge repeatability and reproducibility (GR&R) methodology to evaluate the measurement tools' R&R, NHTSA conducted a GR&R study with the improved tools to determine if the updated tools provided repeatable and reproducible measurements.

NHTSA contracted UMTRI to evaluate the NHTSA-improved tools. The evaluation sought to identify any further improvements that could be made to the tools and to do a GR&R assessment study with the modified tools. NHTSA also required UMTRI to perform a statistical analysis to quantify the usability of the toolsets according to industry standards to address manufacturers' NPRM comments.[50]

UMTRI conducted the GR&R study in two phases to evaluate the effects of different operators, tools, and vehicles. Each phase used 10 different vehicle models for the modified tool evaluations. UMTRI picked the first phase's vehicles based on the 214 vehicles used for the IIHS CRAS study. Phase one vehicles were selected to allow evaluation of the tools and procedures across a range of different seat styles found in the MY 2016 vehicle fleet.[51] For phase two, UMTRI again based vehicle selection on the IIHS CRAS study vehicles, with an emphasis on finding vehicles with lower anchorages in the second-row center (2C) seating position or vehicles with a third row of seats. UMTRI also looked at the data from phase one to identify

[43] Shown on figure 8 of GM's submitted comments in Docket No. NHTSA–2014–0123–0056.

[44] Ex parte memo for September 22, 2015, meeting with FCA. *See* docket NHTSA–2014–0123–0052 and NHTSA–2014–0123–0053 in *www.regulations.gov*.

[45] Ex parte memo for November 23, 2015, meeting with GM. *See* docket NHTSA–2014–0123–0056 in *www.regulations.gov/*.

[46] In June 2015, IIHS released its rating protocol along with tools to assess the usability of the lower anchorages with similar requirements.

[47] Detailed documentation of these changes can be found in the technical report: Louden, A.E., Wietholter, K., & Pruitt, C.E. (2022, May). Evaluation of LATCH Usability Tools Update (Report No. DOT HS 813 229). National Highway Traffic Safety Administration. This report will be available in this final rule's docket.

[48] IIHS developed a tool that included a depth measurement gauge within the AFT.

[49] NHTSA evaluated the IIHS depth tool method that is embedded in IIHS's attachment force tool; however, results showed that the readings using this tool were different from the proposed tool, so NHTSA did not continue to use IIHS's tool for depth measurements. Details can be found in the report: Louden, A.E., Wietholter, K., & Pruitt, C.E. (2022, May). Evaluation of LATCH Usability Tools Update (Report No. DOT HS 813 229). National Highway Traffic Safety Administration. This report will be available in this final rule's docket.

[50] Klinich, K.D., Manary, M.A., Boyle, K., Malik, L., Bowman, P., Flannagan, C.A., ''Evaluation of Repeatability and Reproducibility of Proposed Tools to Assess Lower Anchor Usability'' UMTRI–2018–4, July 2018. This report will be docketed with the final rule.

[51] This analysis is available in the technical report: Klinich, K.D., Manary, M.A., Boyle, K., Malik, L., Bowman, P., Flannagan, C.A., ''Evaluation of Repeatability and Reproducibility of Proposed Tools to Assess Lower Anchor Usability'' UMTRI–2018–4, July 2018.

measures of interest for phase two, such as pick-up trucks and coupe vehicles. In selecting vehicles for the study, UMTRI tried to maximize variation among manufacturers, while also considering the availability to rent such vehicles for testing. UMTRI's GR&R study [52] found that for the clearance angle measurement 92 percent of variance is attributable to the vehicle (part) variability and only 8.4 percent is attributable to system variability (combined variability of the tools, operator, and repeat measurements). For the depth measurement UMTRI found that 93 percent of the variance is attributed to the vehicle (part) variability and only 7 percent to the system variability. For the force measurement, UMTRI found that 67 percent of the variance comes from vehicle (part) variation and 33 percent comes from the system variability. According to the Measurement Systems Analysis Reference Manual (MSA),[53] a system variation in the measurement of 10 percent or less is considered acceptable R&R of the measurement, while a system measurement variability of 30 percent or more is considered unacceptable. The results of UMTRI's GR&R Study demonstrate that the anchorage depth and clearance angle measurements obtained via the updated ADT and CAT have good R&R, but that the anchorage force measurement with the AFT V2 does not. Further details of the GR&R analysis are available in the UMTRI GR&R study report.[54]

c. Summary of Decision on Assessing Usability of Lower Anchorages

This final rule adopts the updated lower anchorage depth and clearance angle tools and requirements, but not the attachment force requirement. These adopted requirements will ensure that lower anchorages on vehicles subject to this rule have sufficient clearance around each lower anchorage, and that the lower anchorages are within 25 mm of the outer surface of the seat bight (anchorage depth).[55] Lower anchorages meeting these requirements will be easier to use, as shown by the UMTRI and IIHS data.

The LATCH Usability study found these ease-of-use specifications correlate with correct child restraint installations. National Child Restraint Use Special Study (NCRUSS) [56] data showed that a loose CRS installation comprises one of the five most significant mistakes consumers make when installing child restraints. Loose CRS installations can result in greater movement of a child and their CRS during a crash, increasing the risk for injury and higher injury severity due to possible contact with vehicle interior structures. CRASs designed to be easier to properly use will increase correct (tight) CRS installations, making children safer in a crash.

The NPRM proposed clearance angle, attachment force, and anchorage depth specifications. This final rule is only adopting requirements and measurement tools for the clearance angle and anchorage depth. The agency evaluated a series of changes to the attachment force tool to improve its R&R. However, the GR&R [57] study found that measurements from the attachment force tool lacked acceptable level of R&R needed for adopting into the standard.[58] NHTSA does not believe further improvements to the attachment force tool will be enough to achieve a sufficient R&R.

UMTRI's LATCH Usability study [59] identified three vehicle hardware characteristics serving as predictors for correct CRS use, analyzing the predicting factors of force and depth separately and together. Depth and attachment force when analyzed separately showed each were highly significant predictors of correct lower anchors use. But when these vehicle characteristics were analyzed together, force became marginally significant while depth remained a highly significant predictor. UMTRI concluded that while these results do not guarantee a causal relationship between depth and correct installations, the results do indicate that depth is a better predictor of correct installations than force.

Although Alliance and FCA commented that only the anchorage depth requirement was warranted, NHTSA disagrees. UMTRI's LATCH Usability in Vehicles Study analyzed depth and clearance angle. Study results concluded that separately they each were highly significant predictors of correct use of lower anchors. When analyzed together, to the extent there is unique variance attributable to depth and clearance separately, depth and clearance angle both became marginally significant. This indicates that both are equally predictive of correct installation.

Because the study could not estimate the contribution of each feature, NHTSA cannot accurately calculate the effect of not having the attachment force as a requirement. The data does indicate that by having clearance angle and depth requirements, correct CRS usage will improve.

d. Detailed Agency Decisions Regarding the Tools and Performance Criteria

1. Clearance Angle Tool and Minimum Allowable Clearance Angle

NHTSA understands that some vehicles will need redesign to meet both requirements. But as presented in figure 9 of the 2015 NPRM,[60] the depth requirement is feasible in many vehicles without making any design changes to meet the S9.2.2(b) requirements. Following careful consideration of comments received and further studies described above, NHTSA has modified the NPRM's proposed clearance angle tool (CAT) to address several concerns raised by commenters. The final design of the CAT now includes a pulley bridge to apply a consistent vertical force of 67 N (15 lb) to address commenters' concerns regarding the difficulty in applying the force in the proposed CAT. Further, although the proposed CAT had digital instrumentation allowing for the recording of time-history data, based on comment feedback, NHTSA has implemented new instrumentation to improve measurement repeatability, including an analog position sensor and an Interface S-Type load cell.

UMTRI's GR&R study found that the measurement variability of the updated CAT [61] system was less than 10 percent of the total measurement variability, confirming that the updated CAT

[52] For details on the vehicles and measurements *see* Klinich et al (2018).

[53] This reference manual, developed by the vehicle industry, contains guidelines for assessing the quality of a measurement system. Down, M., Czubak, F., Gruska, G., Stahley, S., Benham, D. (2010) Measurement Systems Analysis Reference Manual, Fourth Edition. Chrysler Group LLC, Ford Motor Company, General Motors Corporation. *http://www.rubymetrology.com/add_help_doc/MSA_Reference_Manual_4th_Edition.pdf.*

[54] Klinich et.al. 2018.

[55] *See* Anchorage Depth Tool Decision below (section V.d.2), where NHTSA explains why the anchorage depth threshold changed from 20 mm to 25 mm.

[56] Greenwell, N.K. (2015, May). Results of the national child restraint use special study. (Report No. DOT HS 812 142). Washington, DC: National Highway Traffic Safety Administration.

[57] GR&R is the process used to evaluate a gauging instrument's accuracy by ensuring its measurements are repeatable and reproducible. The process includes taking a series of measurements to certify that the output is the same value as the input, and that the same measurements are obtained under the same operating conditions over a set duration. *See https://asq.org/quality-resources/gage-repeatability.*

[58] Klinich, K., Manary, M.A., Boyle, K., Malik L.J., Bowman, P., Flannagan, C.A.'' Evaluation of Repeatability and Reproducibility of Proposed Tools to Assess Lower Anchor Usability'' July 2018. Report will be docketed with this final rule.

[59] Klinich et al., ''LATCH Usability in Vehicles,'' UMTRI–2012–7, April 2012. Link: *https://deepblue.lib.umich.edu/handle/2027.42/90856.*

[60] *See www.regulations.gov/document/NHTSA-2014-0123-0001.*

[61] Identified as CAT V2 in technical reports.

measurements have sufficient R&R for regulatory purposes.

Accordingly, this final rule incorporates the requirement of a minimum of 54-degrees clearance angle in FMVSS No. 225 when applying a 67 N vertical load to the updated tool. Drawings of the final updated CAT design have been incorporated by reference into FMVSS No. 225. NHTSA has placed a copy of the drawings in the docket for this final rule.

While supportive of a clearance angle requirement, Advocates argued that the proposed 54 degree minimum was too low. NHTSA selected the 54-degree clearance angle based on a 50 percent correct CRS use in UMTRI's LATCH Usability study. Only 2 of the 98 vehicles studied by UMTRI had a clearance angle above 75 degrees, which calls into question the feasibility of defining 75 degrees as a limit. The proposed values provide an improvement on correct installations and are not overly burdensome for manufacturers to meet. NHTSA also believes that vehicles will be well above the 54 degree clearance angle, as the standard will also require anchorages depths that typically result in higher clearance angles. Fifty-four of the 98 vehicles in UMTRI's study had clearance angles over 54 degrees (ranging 54–83 degrees), which will improve correct installations beyond the 50 percent used to establish the threshold.

In response to the Alliance's request for clarification on whether the CAT measurements must be made independently or at both anchorages concurrently, the CAT measurements are to be done independently at each lower anchorage in the vehicle. Further, NHTSA does not agree with the Alliance's suggestion that the weight of the tool needs to be subtracted from the total force applied to arrive at the 67 N requirements. With the tool modifications to the CAT, the 67 N will provide a constant load, and subtracting the force due to the weight of the tool would add unnecessary complexity to the system.

NHTSA acknowledges comments made by MGA [62] on the proposed tools and technical drawings published with the NPRM. Specifically, MGA stated that ''the spring pockets are 0.146'' offset, which causes the spring to fall out during compression.'' Based on this, MGA stated that it did the following: (1.) moved the pivot to spring pocket distance as follows: 4.970 − 2.500 = 2.470 (upper spring pocket); (2.) moved the pivot to spring pocket distance as follows: 3.216 − 0.600 = 2.616 (lower spring pocket); (3.) moved the upper spring pocket forward 0.125'' to align the upper and lower spring pocket more closely, and prevent the spring from falling out during compression.

In addition to these changes, MGA pointed out that the load cell presented in NHTSA's NPRM is not commercially available. As such, MGA replaced the load cell with an Interface SSM–AJ–100 load cell. MGA explained the hardware to attach the load cell to the handle and ball and joint connection are Interface CLV–104 clevises. MGA also noted the female rod end is McMaster part number 60645K32, while the male rod end is unchanged. Finally, MGA redefined the clearance angle tool handle measurements to fit the Interface clevis CLV–104 that is used with the Interface SSM–AJ–100 load cell.

In response to these comments, NHTSA has updated the drawings as follows: the dimension 4.97 inches in drawing DA609–001 (figure 9 in MGA comments) is corrected to 5.15 inches to eliminate the offset this dimension created with drawing DA609–003. However, NHTSA did not move the upper spring pocket forward 0.125 inches as suggested by MGA because the spring was modified to a conical spring (in Drawing DA609–000), which prevents the spring from falling out during compression. The upper spring pocket was thus left in the same location as proposed. In response to comments on the load cell, NHTSA updated the drawings as follows for this final rule: the proposed load cell is changed to the S-Type load cell suggested by MGA, which is commercially available. However, suggested changes to the handle and attachments to the handle will not be implemented, as they are now moot as this part was removed and replaced with a pulley system.

Finally, NHTSA acknowledges MGA's request for clarification on certain inconsistent dimensions in two drawings, as seen in figures 17 and 18 of MGA's comments.[63] In response to these comments, this final rule updates the drawings as follows: the material in Drawing DA609–005 is changed from having a material PL 1″ x 1 3/16″ x 1 7/8″ to PL 1″ x 1 3/16″ x 5″ to correct the inconsistent dimensions in the drawing. Further, drawing DA609–006 is removed as the mount in this drawing is no longer needed.

2. Anchorage Depth Tool and Maximum Allowable Anchorage Depth

NHTSA acknowledges that several commenters, including GM and FCA, expressed concerns about the repeatability of the ADT tool and the subjectivity of the viewing angle in determining whether the measurement was 20 mm or less. After careful consideration this final rule's updated ADT [64] addresses concerns over viewing angle subjectivity through the addition of a view bar and zero-strip that translate the viewing angle into a physical measurement. In support of this decision, UMTRI's GR&R study found that the ADT measurement variability of the updated system was less than 10 percent of the total measurement variability (specifically, 93 percent of the variance in the depth measurements is attributed to vehicle variation and only 7 percent to the system variability), confirming that the updated ADT measurements have sufficient R&R for regulatory purpose.

This final rule is also increasing the NPRM's proposed 20 mm limit to 25 mm. As noted earlier, since the study vehicles were selected based on their different characteristics and not as a randomized selection, the agency's analysis does not fully evaluate the variability across vehicles. There could be some anchorage depth measurement variability in some seat designs. Further, the GR&R study by UMTRI considered depth measurements rounded to the nearest quarter cm. In acknowledgment of these limitations in the GR&R analysis, NHTSA is specifying that the anchorage depth be 25 mm or less, rather than the 20 mm proposed in the NPRM. As such, measurement by the finalized ADT will account for measurement and manufacturing variability. Expanding the depth requirement to 25 mm will still result in improved usability and a higher number of correct installations.[65]

NHTSA did not consider lowering the anchorage depth to less than 20 mm, which would be a more stringent threshold than that proposed in the NPRM. In response to the Alliance's comment asking why a 4 cm anchorage depth was not proposed, as that depth also showed correct installations in UMTRI's LATCH Usability study, NHTSA points out that the UMTRI LATCH Usability study found that study

[62] For full comments and associated figures *see www.regulations.gov/comment/NHTSA-2014-0123-0049.*

[63] Docket No. NHTSA–2014–0123–0049.

[64] Identified as ADT V4 in technical reports.

[65] UMTRI's LATCH Usability study (2012) was not conducted with the precision tools such as the ADT included in this final rule. The UMTRI Study tools had some ambiguities regarding a consistent viewing angle to detect the change in color from the hook-type tool. The additional 5 mm is in the realm of depth reading variability from that study.

volunteers correctly installed CRSs 50.7 percent of the time when using anchorages with depths 2 to 4 cm,[66] but that anchorage depths of 0 to 2 cm showed a more pronounced improvement to 85.9 percent correct CRS installation. As a 35 percent increase in the number of correct CRSs installed is a significant increase in the crash safety protections provided to young children, the Agency declines to consider a 4 cm anchorage depth for this final rule. In response to the Alliance's suggestion to better define the tensioning and angle placement of the ADT during the procedure, as the updated ADT is pulled taut so that the anchorage bar engages the tool, a need to define the tension does not exist, as the required tool is rigid.

NHTSA is rejecting a comment requesting the removal of the prohibition in FMVSS No. 225 on stowable lower anchorage bars, as lower anchorages should be readily available for use and no further steps should be necessary (other than removing a lower anchorage specific cover) to access and use them.

NHTSA agrees with GM's recommendation to position the ADT at an angle parallel to the seat cushion to make measurements and has revised the NPRM's proposed procedure to specify that the ADT will be positioned at an angle parallel to the seat cushion. The test procedure will indicate how to measure the seat cushion angle (using a 2 ft level and an inclinometer) and how to position the ADT to reach this angle (use of shims if necessary). In response to expressed concerns over the measuring tool potentially displacing the trim covering or surrounding trim being displaced by the tool, NHTSA notes that this final rule's anchorage depth measurement procedure allows for clear depth measurement via the taping away from anchorages (with masking tape) such things as coverings, flaps, or other vehicle parts. In relation to concern over trim coverings, including slits where the fabric or leather is too stiff to be taped, there should be minimal manipulation of the slit to introduce and hook the ADT in the anchorage and pull it back. The ADT may push away some of the fabric or leather when it is engaged to the lower anchorage. The depth will be measured where the viewing strip comes in contact with the vehicle seat (which includes the fabric or leather). Since the vehicle is prepared before the test measurement by marking the vehicle seat with a line perpendicular to the anchorage center, the tool can be easily directed to the anchorage.

In response to commenters that suggested developing a depth measure based on a hard point given the difficulty in designing and controlling the variance of the foam/trim elements during the design process, NHTSA respectfully disagrees with this suggestion. The LATCH Usability study[67] found that anchorages positioned less than 20 mm from the seat bight result in more correct installations. Further, one noted issue consumers experience when installing CRSs with deep anchorages is difficulties with the foam of the seat and/or the fabric/leather surrounding the anchorage. As anchor depth measurement from a hard point measurement does not take the interactions of the seat foam and fabric into consideration, a depth measurement based on a seat hard point would not necessarily improve ease-of-use and correct installations. NHTSA does acknowledge that there may be greater variability in foam and different trim levels than those considered in the UMTRI GR&R analysis. To account for any potential measurement or manufacturing variability this final rule specifies an anchorage depth of no more than 25 mm, as opposed to the proposed 20 mm, to account for measurement and manufacturing variability.

Several commenters expressed concerns over the costs of required tooling changes to meet the depth requirements of this final rule. NHTSA acknowledges that tooling changes for existing production vehicles can be very costly and are better accommodated during the early design stage of a vehicle's renewal cycle to minimize any potential costs. Accordingly, the agency finds good cause to provide more lead time and a phase-in for manufacturers to account for different trims and the possibility of tooling changes to meet the depth requirements required by this final rule. As such, this final rule is providing a longer lead time than that proposed in the NPRM, with a phase-in schedule (*see* Lead Time Section). NHTSA is permitting optional early compliance with this final rule's requirements.

3. Attachment Force Tool

Following careful consideration of comments received and additional testing, NHTSA has decided not to adopt the NPRM's proposed attachment force requirements into FMVSS No. 225. Following publication of the NPRM, NHTSA attempted to improve the R&R of the AFT. However, UMTRI's GR&R study, which used the improved AFT, found that 67 percent of depth measurement variance came from vehicle (part) variation and 33 percent came from system variability (variability attributed to the tools, operators, and repeated measurements). The Measurement Systems Analysis Reference Manual (MSA)[68] document, followed by the vehicle industry, indicates that when evaluating a test procedure, it is acceptable if the system's percentage variation is less than 10%. This means the improved AFT failed to reach an acceptable R&R for adoption into the standard. NHTSA does not believe further improvements to the AFT would achieve sufficient repeatable and reproducible measurements for regulatory purposes. Further, although Ford suggested using the average of several measurement trials using the AFT as the criteria for anchorage attachment force, NHTSA found R&R was not sufficiently improved by considering the average of five measurement trials for some vehicle seats. As NHTSA has determined the adoption of the AFT into FMVSS No. 225 is not feasible, this final rule does not address additional comments received suggesting improvements to the tool.

Despite the decision not to include an attachment force criterion into FMVSS No. 225, the remaining requirements of this final rule will improve the ease-of-use of the lower anchorages. UMTRI's study[69] identified the characteristics of attachment force, clearance angle, and attachment depth as predictors for correct CRS use, and then modeled the predicting factors of force and depth both separately and together. Analyzed separately, depth and attachment force were highly significant predictors of the correct use of lower anchors. Analyzed together, depth remained a highly significant predictor, while attachment force was only a marginally significant

[66] The UMTRI ''LATCH Usability'' study showed correct use of 85.9 percent, 50.7 percent and 43.1 percent for lower anchorage depths of 0–2 cm, 2–4 cm and 4–6cm respectively. We expect lower anchorages with depths between 2–4 cm that are closer to 2 cm would have higher correct use and those closer to 4 cm would have lower correct use.

[67] Klinich et al., ''LATCH Usability in Vehicles,'' UMTRI–2012–7, April 2012. Link: *https://deepblue.lib.umich.edu/handle/2027.42/90856.*

[68] Down M, Czubak F, Gruska G, Stahley S, Benham D. (2010) Measurement Systems Analysis Reference Manual, Fourth Edition. Chrysler Group LLC, Ford Motor Company, General Motors Corporation. Link: *http://www.rubymetrology.com/add_help_doc/MSA_Reference_Manual_4th_Edition.pdf.*

[69] Klinich et al., ''LATCH Usability in Vehicles,'' UMTRI–2012–7, April 2012. Link: *https://deepblue.lib.umich.edu/handle/2027.42/90856.*

predictor. As such, UMTRI concluded that although these results do not guarantee a causal relationship between depth and correct installations, they do indicate that depth is a somewhat better predictor of correct CRS installations than attachment force. This final rule's depth requirements ensure that the lower anchorages will be placed in a more forward position, making them more likely to avoid foam material and structures and potentially resulting in decreased force needed to attach the lower anchorage. Further, this final rule's required clearance angle will ensure no material or structure will prevent placement of the lower anchorage attachment, which may also result in less required force to attach the lower anchorage.

VI. Improving the Ease of Using the Tether Anchorage

FMVSS No. 225 currently requires vehicle manufacturers to equip vehicles with a tether anchorage at three rear designated seating positions (two of these positions are also required to be equipped with lower anchorages). Tether anchorages must be in a specified zone accessible without the need for any tools other than a screwdriver or coin. Tether anchorages must be easy to use, as they are the primary factor behind the estimated 36–50 lives saved a year following NHTSA's adoption of FMVSS No. 225.[70]

To further improve the usability of the tether anchorage by making it easier for customers to recognize and access, the NPRM proposed the following requirements:

- Reduce the zone in which a tether anchorage must be located to prevent tether anchorages from being placed deep under a vehicle seat.
- As some tether anchorages are too close to a structure, such as a head restraint, specify a minimum 165 mm (6.5 in) distance from a specified reference point on the vehicle seat to the tether anchorage to allow for the tightening of the tether strap. This requirement will ensure that adequate clearance is provided to tighten the tether strap.[71]
- Tether anchorages must be accessible without the need for any tools other than a screwdriver or coin, and without folding the seatback or removing carpet or other vehicle components. The tether anchorage could be covered with a cap, flap, or cover, provided that the cap, flap, or cover is specifically designed to be opened, moved aside, or to otherwise give access to the anchorage without the use of any tools and is labeled with a specific symbol indicting the presence of the tether anchorage underneath.
- Requiring a standardized rigid bar so consumers could more easily recognize and find it, as currently some tether anchorages are made from flexible webbing.
- Standardizing the tether anchorage marking by requiring that it match a marking on the child restraint system tether and be placed within a specified distance from the anchorage.

General Comments

Commenters almost unanimously supported improving the ease-of-use of tether anchorages but differed in their views on specific NPRM proposals. Overall, child restraint manufacturers and private individuals supported the proposed improvements to the ease-of-use of the tether anchorage. SRN and an individual, Dr. Baer,[72] agreed on the standardization, accessibility, and clearance (165 mm distance to tether anchor) proposals to improve tether use. However, Dr. Baer disagreed with allowing tether anchorage covers, stating that they hide a safety feature. SRN and Dr. Baer expressed concerns over some tether anchorage designs concealed by other vehicle structures, making them difficult to access. IIHS also supported reducing the allowable zone for tether anchorages to better align allowable locations with the locations parents expect to find tether anchorages. Safe Kids[73] expressed support for a harmonized, consistent, and easily understood way to identify and use the CRAS.

In contrast, the Alliance and several vehicle manufacturers objected to the proposed requirements to reduce the zone where top tethers could be located, including specifically to the proposed tether anchorage location on the package shelf[74] behind second-row seats in vehicles such as sedans. The Alliance stated that many passenger cars that have the tether anchorages conveniently located in the package shelf behind the seat will not meet the proposed 165 mm minimum wrap around distance. The Alliance explained that current design locations that would be precluded by the proposed requirements do, in fact, enable effective attachment since the path over a fixed head restraint or under an adjustable head restraint provides additional wraparound distance to tighten the tether strap. Several vehicle manufacturers stated that the proposed requirement would force the relocation of tether anchorages rearward in the vehicle, resulting in less hand clearance to the vehicle backlight[75] window for manipulating the tether hook. Vehicle manufacturers also expressed concern over costly repackaging of components such as speaker assemblies that currently occupy the space where the tether anchorage would have to be placed. Some commenters urged NHTSA to use a point farther forward in the vehicle's seat than the proposed SB point, explaining the SB point is not a reference that can be found on all of their vehicles.

The Alliance and several vehicle manufacturers sought clarification on some terms related to the reduced tether anchorage zone under the seat, and also commented on other proposed provisions for improving the ease-of-use of tether anchorages (*e.g.,* accessing tether anchorages without tools, accessing tether anchorages without folding the seatback or removing carpet or other vehicle components, such as luggage compartment security covers, and using rigid bars in light trucks). Commenters also expressed concerns with the proposed requirements based on their implications and costs. Vehicle manufacturers generally commented that the proposed 3-year lead time is insufficient to account for necessary changes, and many asked for a phase-in of the requirements.

a. Attaching to the Tether Anchorage

Tether Anchorage Accessibility—Zone Under the Seat

To promote accessible tether anchorages, current FMVSS No. 225 requires that tether anchorages be located within the shaded zone shown in figures 3 through 7 of FMVSS No. 225 for the designated seating position (DSP) where the anchorage is installed. In considering changes to FMVSS No. 225 to further increase tether anchorage accessibility, the agency first evaluated vehicle fleet data to better understand where tether anchorages are currently located. The evaluation found that the most common tether anchorage

[70] 64 FR 10786.

[71] The NPRM also proposed amending FMVSS No. 213 to limit the length of the CRS tether hardware assembly (which consists of a tether hook and hardware to tighten and loosen the tether strap) to 165 mm (6.5 in) so that the tightening mechanism can be easily used in the clearance space around a tether anchorage.

[72] Dr. Baer is a pediatrician, advocate and nationally certified child passenger safety instructor best known as The Car Seat Lady.

[73] Safe Kids is a network of organizations working to prevent unintentional childhood injury, the leading cause of death and disability for children ages 1 to 14.

[74] The shelf behind the rear seat in a sedan.

[75] Backlight is the rear windshield or back window glass in a vehicle.

locations are the seatback (41 percent), the package shelf (37 percent), the back wall of the occupant compartment (8 percent), the roof (6 percent), the floor (4 percent), and under the seat (3 percent). NHTSA contemplated the merits of designing the NPRM to considerably limit the zones in figures 3 through 7, but decided against this approach following review of NHTSA's test data. This data showed that the current allowable locations of tether anchorages do not increase the risk of injuries, as their performance and loading to the anchorages are very similar to tether anchorages that are centered and closer to the seat. Further, NHTSA acknowledges that vehicle manufacturers must consider many factors in deciding where to place a tether anchorage, including the strength of the structure to which the tether anchorage is affixed, the degree to which the tether anchorage—or the child restraint, when using the anchorage—interferes with ingress, egress, seating, and/or the comfort and safety of vehicle occupants. Due to these considerations, vehicle manufacturers sometimes install tether anchorages slightly off-center to a seating position, or on the roof, floor, or back wall. Recognizing there is merit in providing flexibility to manufacturers to balance where to locate the anchorages, the agency decided not to considerably narrow the zones in figures 3 through 7.[76] Instead, the NPRM sought to improve the ease of using tether anchorages via other means.

First, the agency proposed to reduce the allowable zone under the seat, because the shaded zone shown in figures 3 through 7 encompasses a wide area that has resulted in some tether anchorages being located where consumers have had difficulty accessing them, such as deep under the seat where folding the seat is required to reach/attach the tether anchorage.[77] As such, NHTSA proposed to amend figures 3 through 7 in the standard to disallow tether anchorages from being placed deep under the seat. Specifically, the agency proposed that the forwardmost edge of the allowable tether anchorage zone represented by the shaded area in figure 3 of the standard be moved rearward to a position defined by the intersection of the vehicle floor with a plane parallel to the torso line reference plane passing through the rearmost point of the bottom of the seat at its centerline.[78]

Comments Received

Vehicle manufacturers generally disagreed with the proposal laid out in the NPRM. Global stated that for certain vehicle designs the bottom of the seat may be the most suitable location for the anchorages and requested that the agency permit continued use of the bottom of the seat for tether anchorages if the manufacturer includes appropriate markings on the seatback to alert consumers to the anchorage location. The Alliance argued the proposal to restrict the allowable tether zone under the seat may be appropriate for passenger cars with limited space under the seat, but it unnecessarily limits the location of the anchorage for mini-vans, vans and some SUVs. The Alliance provided figures in its comments[79] showing a full-size van rear seat with the upper tether anchorage located on the seat structure forward of the forward-most limit of the proposed zone and explained that the location provides a readily accessible upper anchorage point formed into the seat. The Alliance stated the proposed acceptable zone would require additional anchorage hardware that would need to be welded to the seat structure. The Alliance explained that because the current design is stamped into the existing seat structure, manufacturers can voluntarily provide additional anchorages at very low cost (*i.e.,* the 10-seat version of this full-size van has eight tether anchorages available for use). The Alliance opined that there is no need to revise the zone such that these tether anchorages would no longer be permitted, given the easy access and visibility of tether anchorages.

Similarly, Ford commented that the proposal to limit the tether anchorage location using a plane that is parallel to the torso line that passes through the ''rearmost point of the bottom of the seat'' is overly restrictive for some free-standing seats (*i.e.,* SUVs and vans). Ford suggested basing the forward-most limit of the acceptable zone on the SgRP. Ford proposed using a vertical plane 120 mm rearward of the SgRP as the forward limit of the acceptable zone, which would remove the ambiguity regarding the ''rearmost point of the bottom of the seat'' and, combined with labeling, permit some currently existing under-seat designs that do not have accessibility issues. Ford added that the plane is already specified in the standard to define the forward-most limit of the lower anchorage acceptable zone. Ford included three illustrations[80] depicting the current allowable under-seat zone, the allowable zone proposed in the NPRM, and a modified proposal that would limit the anchorage location to the plane 120 mm rear of the SgRP.

The Alliance and Honda requested clarification on how to define the intersection of the vehicle floor with a plane parallel to the torso line reference plane passing through the rear-most point of the bottom of the seat at the centerline of the seat. Both the Alliance[81] and Honda[82] presented illustrations of different scenarios where they indicated the rearmost point of the bottom seat was unclear and requested clarification.

In addition, the Alliance explained that tether anchorages cannot be in the seatback if the seatback plane is located anterior[83] to the proposed line in figure 3 of the proposed regulatory text in the NPRM. To prevent misinterpretation, the Alliance recommended removing the line from figure 3 in the proposed regulatory text in the NPRM or amending the requirement to call out this line as a line that represents the vehicle specific seatback surface within the prescribed zone, for the seatback profile similar to the callout for the vehicle floor pan.

[76] IIHS was the sole commenter that encouraged NHTSA to further reduce the allowable zone for tether anchorages to better align allowable locations with where parents expect to find tether anchorages. While NHTSA agrees a more reduced zone would place tether anchorages where consumers may be more likely to anticipate them, the agency must also consider other factors a vehicle manufacturer has to weigh when deciding the location of tether anchorages. Manufacturers consider factors such as strength of the structures, features that the manufacturer may design into seats such as pass through openings, seat back folding mechanisms that may cause the tether anchorages to be in the back of the seat, and other design considerations. Thus, NHTSA is not reducing the zones in this rulemaking.

[77] This deep under the seat location is the forward-most edge of the area under the vehicle seat. The location is defined by the intersection of the torso line reference plane (defined by the 2016 SAE J826 two-dimensional drafting template) and the floor pan.

[78] Vehicles with tether anchorages located deep under the seat where the seat must be folded to reach the anchorages are no longer manufactured, so this change in requirements will have little or no impact on current vehicle designs. However, the amendment is needed to prevent these designs from coming back into the fleet.

[79] Figure 3 of Docket No. NHTSA–2014–0123–0027.

[80] Ford's illustrations can be found in figure 3 of Docket No. NHTSA–2014–0123–0026.

[81] Alliance's illustrations can be found on pages 8–9 of Docket No. NHTSA2014–0123–0027.

[82] Honda's illustrations can be found on pages 3 of Docket No. NHTSA2014–0123–0017.

[83] The Alliance's illustrations can be found on pages 9 of Docket No. NHTSA2014–0123–0027.

Agency Response

Comments expressing concerns over how the NPRM proposed to define the rearmost point of the bottom of the seat to locate the plane setting the limit of the allowable zone have merit. Therefore, following careful consideration and evaluation, this final rule adopts requirements to specify the allowable tether anchorage zone under the seat using a vertical plane 120 mm rear of the H-Point to define the allowable limit.

Commenters presented several scenarios in which defining the rearmost point of the bottom of the seat was not possible, as the proposed requirement did not provide sufficient details on how to precisely define it. Commenters also stated that some existing easily accessible tether anchorages near the back of but slightly under the seat may not be compliant with the proposed tether anchorage zone. These anchorages are considered easily accessible because the seats do not require folding to access the anchorages and the anchorages can be easily identified since they have the proposed markings.

In acknowledgment of these concerns the Agency did a series of installations and measurements to evaluate whether the vehicles with existing tether anchorages near the back but slightly under the seat are easy to use, and to determine whether the zone under the seat suggested by Ford is appropriate to define the allowable tether zone under the seat.[84] NHTSA selected three vehicles (2015 Toyota Sienna, 2018 Freightliner Sprinter, and 2020 Ford Transit) with tethers located low on the seatback (similar to the ones commenters stated were easily accessible locations) to evaluate whether they were easily accessed when installing a CRS, whether the tether anchorage location would fail to be located within the NPRM's proposed allowable tether anchorage zone, and whether it would be within the Ford-proposed allowable tether anchorage zone (defined by a vertical plane 120 mm rearward of the SgRP as the forward limit of the allowable tether anchorage zone).

In conducting the evaluation, NHTSA installed the Evenflo Triumph and the Britax Advocate Clicktight in the three selected vehicles to determine whether the tether was easily installed. The trials showed that the tether anchorages were easy to locate and use for attaching the CRS tether anchor connectors.

NHTSA defined the allowable tether zones under the seat using both the NPRM's proposed zone (parallel torso reference line that passed through the rearmost point of the bottom of the seat) and Ford's proposed zone (defined with a vertical plane 120 mm rearward of the H-point) [85] in the three selected vehicles. These measurements were performed to verify whether Ford's proposed method for defining the allowable tether zone under the seat would remove the ambiguities present in the NPRM's proposed zone, and to evaluate whether the tether anchorages in the vehicles are located within the NPRM's proposed allowable zone and/or Ford's proposed zone (but using the H-point rather than the SgRP suggested by Ford).

The evaluations confirmed that defining the tether anchorage zone with the vertical line 120 mm behind the H-point removed the ambiguities contained in the NPRM's proposed method. The evaluations showed that the tether anchorages of all three vehicle seats were easy to access and use for installing child restraints. However, these tether anchorages would not meet the allowable tether anchorage zone proposed in the NPRM, while they would pass using the 120 mm behind the H-point measurement method. This result indicates that an allowable tether anchorage zone determined as a plane 120 mm rearward of the H-point better reflects ease of access and use of the tether anchorages than the NPRM's proposed allowable zone.

TABLE 1—SUMMARY OF TETHER ANCHORAGE LOCATION WITH RESPECT TO THE NPRM'S PROPOSED ALLOWABLE TETHER ANCHORAGE ZONE AND THAT DETERMINED AS A PLANE 120 mm BEHIND THE H-POINT

Year	Manufacturer	Model	Seat position	Current zone	NPRM zone	Final rule zone (120 mm behind H-point)
2015	Toyota	Sienna	2nd Row Driver Outboard.	Pass	Fail	Pass.
2018	Freightliner	Sprinter	2nd Row Passenger Outboard.	Pass	Fail	Pass.
2020	Ford	Transit	2nd Row Passenger Outboard.	Pass	Fail	Pass.

The NPRM's proposed requirement sought to eliminate tether anchorages located deep under the seat where folding the seat is necessary to reach it. NHTSA believes the limit on the tether anchorage location under the seat defined by a vertical plane 120 mm rear of the H-Point meets this intent. NHTSA also concludes that using a vertical plane 120 mm rearward of the H-point is easily defined, removes ambiguities commenters noted in the NPRM's proposed tether anchorage zone, and better reflects the accessibility and usability of the tether anchorages. Therefore, the agency is adopting requirements to specify the allowable tether anchorage zone under the seat using a vertical plane 120 mm rear of the H-Point to define the allowable limit. This requirement will prevent tether anchorages from being located deep under the seat where they are difficult to access, addressing comments received.

b. Tightening the Tether

NHTSA proposed requirements to make it easier for a consumer to attach a child restraint tether hook to a tether anchorage and tighten the tether strap. Currently, FMVSS No. 225 specifies that tether anchorages must be located within the shaded zone shown in figures 3 to 7 of the standard for the DSP

[84] Evaluation of FMVSS No. 225 Tether Anchor Zones Under the Seat. May 2022. Kedryn Wietholter, National Highway Traffic Safety Administration. Evaluation summary will be docketed along with this final rule.

[85] NHTSA chose to use the H-point as it can be measured in the laboratory as opposed to the SgRP, which is a manufacturer-defined point. Both points are very similar.

in which the anchorage is installed.[86] NHTSA proposed to amend FMVSS No. 225 to require that tether anchorages have clearance space for tightening the strap.

The NPRM proposed to require a 165 mm (6.5 in) minimum distance from each tether anchorage to a seat-based reference point for each designated seating position (DSP) with a tether anchorage. In 2012 the LATCH Usability study[87] found that, under the current FMVSS No. 225, tether anchorages can be located too close to the head restraint, on top of the seatback, or the tether attachment point on a CRS, resulting in insufficient clearance to tighten the CRS tether strap. The study reviewed the tether hardware assembly on 21 child restraint systems made by 11 different CRS manufacturers.[88] The review found the tether hardware assembly of the 21 child restraints ranged from 102 to 184 mm (4 to 7.2 in) in length, with 15 CRSs having tether hardware assembly lengths between 140 mm (5.5 in) and 165 mm (6.5 in). The study suggested that having tether anchorages on a package shelf or behind the seatback at a distance of at least 165 mm (6.5 in) rearward or below the back of the head restraint or top of the seatback for DSPs without a head restraint would provide greater clearance for attaching the tether hook of a CRS and tightening the strap.

In drafting the NPRM NHTSA reviewed the LATCH usability study and tentatively determined that specifying a minimum 165 mm (6.5 in) distance from the tether anchorage to a defined reference point on the vehicle seat would improve tether anchorages' ease-of-use. The NPRM explained that this clearance would allow for the tightening of tether straps in most vehicles without interference from other structures, such as the head restraint.

[86] The standard specifies a reference point ''W'' that is 50 mm (1.9 in) below and 50 mm (1.9 in) rearward of the shoulder reference point (R-point), and a reference point ''V'' that is 350 mm (13.7 in) vertically above and 175 mm (6.8 in) horizontally back from the H-point. The standard also specifies a strap wrap-around length of 200 mm (7.8 in) from the W-point and a strap wrap-around length of 250 mm (9.8 in) from the V-point (*see* figure 4 of FMVSS No. 225). Tether anchorages may be located only within the zone that is generated using both reference points and their associated strap wrap-around lengths to ensure there is sufficient distance for a tether strap and hook to be attached to the anchorage.

[87] Klinich, K.D., Flannagan, C.A., Manary, M.A., and Moore, J.L. ''LATCH usability in vehicles.'' Link: *http://deepblue.lib.umich.edu/handle/2027.42/90856.* The report was sponsored by IIHS for developing IIHS's rating of the usability of the child restraint anchorage systems in various vehicles. *See* IIHS Status Report: Vol. 47 No. 3, April 12, 2012. *http://www.iihs.org/sr/default.aspx.*

[88] This hardware consists of the tether hook and hardware to tighten and loosen the tether strap.

The NPRM proposed that the reference point on the vehicle seat, which NHTSA designated as ''SB,'' be defined as the intersection of the plane parallel to the torso line reference plane (defined in figure 3 of FMVSS No. 225) that passes through the rearmost point of the seat and the wrap-around line from the ''V-point'' to the tether anchorage.[89] The agency noted that both the V- and W-point could have been used for determining the vehicle seat reference point SB. NHTSA selected the V-point to define the reference point because it would encompass both low mounted and high-mounted tether straps.

1. Tether Anchorage Location—165 mm to a Reference Point

Comments on 165 mm Distance to Reference Point

In response to the NPRM many vehicle manufacturers stated that requiring manufactures to move tether anchorages to locations meeting the 165 mm (6.5 in) specification is impractical within current styling because substantial vehicle components currently occupy the locations. The Alliance stated that the relocation of a single component has implications for other design considerations including, but not limited to, wiring harnesses, body in white attachments and reinforcements, electromagnetic interference, and radio-frequency interference re-qualification. FCA stated that moving the tether anchorages rearward would force a complete redesign of the package shelf, including re-packaging of the existing package shelf components as well as moving the reinforcements. FCA said that if speakers or modules must be relocated to the door or the trunk changes to these components would also be necessary, including side impact countermeasures, door electrical wire harnesses, and interior trim modifications. The Alliance added that many passenger cars with tether anchorages located in the package shelf behind the seat will not meet the proposed 165 mm minimum wrap around distance,[90] even though the anchorages are easy to use.

Many vehicle manufacturers, the Alliance, and Global stated that tether anchorage distance and CRS hardware incompatibility should be addressed in FMVSS No. 213 by limiting the size of the tether hook and other CRS attachment hardware.[91] Some vehicle manufacturers and the Alliance provided data on the sizes of tether hooks and hardware in stating that the lack of uniformity in CRS attachment hardware and its mounting location on the CRS point to the actual source of the compatibility issue, rather than the vehicle ''swing zone'' behind the seatback or head restraint. Hyundai stated that tight installations can be achieved even with vehicles that have less than the proposed 165 mm (6.5 inches) distance, with a CRS tether hardware and strap measuring 170 mm (6.7 inches).

The Alliance and Toyota identified potential problems with applying the proposed procedure to certain vehicles regarding the definition of the point SB. They presented a case for some head restraints where the torso reference plane may not intersect the strap wrap around line. Therefore, for this type of head restraint, the reference point SB does not exist. The Alliance and Toyota also presented a case in which the reference point SB cannot be defined when the seatback angle is larger than the torso angle.

Toyota requested that NHTSA develop a repeatable and feasible requirement regarding the distance from the tether anchorage to the DSP. Toyota suggested that because the existence of reference point SB is dependent on the rearmost point of the seat, which can vary dramatically based on seat design, one potential method to solve this issue would be to develop a new tool to measure the distance of 165 mm from the tether anchorage instead of using the concept of reference point SB.

Several commenters also suggested an alternative way of defining a clearance zone. FCA recommended a general redefinition of the reference point SB without providing a suggested definition. The Alliance opined that the proposed minimum wraparound distance, measured from point SB, is unnecessarily stringent and does not take current CRS installation practices into account. The Alliance and Honda recommended that a point farther forward in the vehicle DSP, representing a tether attachment point on a child restraint, would provide a more practicable reference point for this measurement.

Britax stated that mandating a minimal vehicle interior distance should facilitate better tether

[89] The rearmost point of the seat includes the head restraint if one is present. The V-point represents a low-mounted tether strap on a CRS and the W-point represents a high-mounted tether strap on a CRS.

[90] The term wrap around distance is a distance measurement made using a flexible tape measure. One end of the tape is held at a defined point, the tape is wrapped around desired structures, and held taut at a second defined point.

[91] The NPRM proposed to limit the tether hook and hardware to 165 mm (6.5 in).

installation, particularly in sedan vehicles with rear windows close to rear seatbacks. Britax anecdotally noted it has experienced situations where the distance between the vehicle seat and tether anchorage would not permit proper tether attachment and tightening. UMTRI supported the implementation of a 165-mm clearance around the tether anchorage in vehicles and the regulation of a maximum adjusted length of the tether attachment hardware to 165 mm to improve compatibility. UMTRI noted that these recommendations were based on usability testing of CRS with a single strap tether.

Post NPRM Research

UMTRI Research

After carefully reviewing comments that raised concerns over the proposed 165 mm tether anchorage clearance criterion, the agency determined that it was appropriate to task UMTRI with conducting a study [92] to: (1) define an alternate reference point to the proposed SB point that would be more practical, (2) ensure that the requirements do not interfere with Australian Design Rule (ADR) 34/2,[93] (3) estimate the number of vehicles that may need modification to meet clearance criteria based on the proposed and alternative reference points, and (4) evaluate alternative ways of ensuring tether tightness.

In carrying out its study UMTRI used two data sets to estimate the proportion of vehicles that would meet the proposed 165-mm clearance criteria. First, UMTRI surveyed 60 top selling 2012–2013 MY vehicles to collect data on each vehicle's tether anchorage location, head restraint characteristics, and tether routing path. UMTRI used a rigid 165-mm gauge with tether hook to evaluate whether the tether anchorage location met the proposed criteria. This data set showed that 21 of the surveyed vehicles had tether anchorages on the rear package shelf. Eighteen of these vehicles were sedans and three were pickup trucks. Of the sedans, only one met the proposed criteria. For the 17 sedans that did not meet the NPRM's proposed criteria, routing the tether over the head restraint improved access to the tether hardware.

UMTRI surveyed photos of the 21 vehicles with a tether in a package shelf to evaluate potential barriers in moving the tether anchorages. About half of the vehicles had no visible barriers at outboard seating positions, two vehicles had potential for interference from rear window glazing during installation, and the remaining vehicles had speakers in the way. The center seating position in 5 vehicles had rear defroster structures that may be in the way of relocation.

The second data set used a survey of 98 top selling 2010–2011 MY vehicles. The tether anchorage location was measured for these vehicles via wraparound distance relative to an estimated shoulder reference point. These surveys collected photos that helped identify structures that would hinder any tether anchorage relocation if the 165 mm criterion was not met. Data from the 98 vehicle-dataset showed that 44 percent of vehicles with the tether anchorage on the seatback would meet the 165 mm criterion. Of the 35 vehicles with the tether anchorages located in the package shelf of the outboard seating position, 24 percent would not meet the 165 mm criterion, but could improve usability if the tether was routed over the head restraint.

UMTRI then developed an alternate reference zone using established reference points such as the H-point (hip point) and the R-point (shoulder point) using 21 vehicles (MY2010–2014) scanned by UMTRI during previous projects.[94] A circle with a 325 millimeter radius centered on the R-point and truncated 230 mm below its center was used to create the limits of the allowed tether anchorage zone.

UMTRI evaluated 11 SUVs and trucks in the scanned vehicle dataset [95] that had an upper seatback tether anchorage location. To avoid conflicts with the IIHS usability rating criteria [96] the circle was truncated at 230 mm below the R-point. Doing so allowed for the tether anchorage to be located far enough to ensure tightness while not conflicting with IIHS usability rating criteria.

UMTRI evaluated the proposed and alternative tether anchorage clearance criteria against 20 of the 21 [97] scanned vehicles (MY2010–2014) to determine whether vehicles met the proposed distance criteria and quantify the distance a tether anchorage would have to be relocated if that vehicle did not meet the proposed or alternative criteria. Results were mixed.[98] Eleven models met both criteria. Four failed both criteria but using the alternative criterion the tether anchorage relocation distance was shorter than for the 165 mm clearance criterion. Two passed the alternative criterion but failed the 165 mm criterion. Two vehicles with tether anchorages in the upper seatback (and not the package shelf) passed the 165 mm criterion but failed the alternative criterion. For these two vehicles, tightening the tether was difficult for installing some child restraints. The tether anchorages for these two vehicles would need to be moved 1–2 mm lower to meet the 325 mm truncated sphere zone, which would also permit tightening the tether.

UMTRI also performed in-vehicle evaluations for both tether anchorage clearance criteria on 10 vehicles (MY 2004–2014).[99] For this set of vehicles UMTRI found that three vehicles failed both criteria, while seven met both criteria. Of the three vehicles that failed both criteria, the distance to move the tether anchorages to meet the alternative criterion was shorter than that for meeting the proposed criterion in two vehicles.

In its review of the two vehicle surveys UMTRI found that about one-third of vehicles had tether anchorages located on the package shelf and that the majority did not meet the 165-mm criteria if the tether strap was specified for routing under the head restraint. However, UMTRI found that in most of these vehicles routing the tether strap over the head restraint provided good access to the tether adjuster hardware.

VRTC Research

Following review of the UMTRI study, VRTC evaluated the alternative criterion (zone based on a 325 mm circle centered on the R-point), the proposed 165 mm clearance distance, and the

[92] Klinich, K.D., Boyle, K., Orton, N.R., Manary, M.A., & Ebert, S. (2016, January). *Investigation of clearance criterion between tether anchor and head restraint.* Ann Arbor: University of Michigan Transportation Research Institute. Report will be docketed alongside this final rule.

[93] ADR 34 Link: *https://ablis.business.gov.au/service/vic/australian-design-rule-adr-34-child-restraint-anchorages-and-child-restraint-anchor-fittings/24383.* This standard specifies a clearance around the tether anchorage to enable access and attachment of the tether hook to the anchorage.

[94] *See* Table 1 in the report titled ''Investigation of clearance criterion between tether anchor and head restraint'' by UMTRI. Report will be docketed along this final rule.

[95] The other 10 vehicles were sedans.

[96] IIHS LATCH usability rating considers tether anchorages located in the top 85 percent of the seat back as ''good.'' The IIHS LATCH Usability Rating Guidelines can be found here: *www.iihs.org/media/8f828313-d122-4d27-a3b0-f2b8ec60065d/wOdYVA/Ratings/Protocols/current/LATCH_rating_guidelines.pdf* (last accessed 4–16–2024).

[97] The Ford F150 was not evaluated, as pickup trucks have different geometry.

[98] *See* Table 1 in UMTRI's report for detailed results. Klinich, K.D., Boyle, K., Orton, N.R., Manary, M.A., & Ebert, S. (2016, January). *Investigation of clearance criterion between tether anchor and head restraint* (Report No. UMTRI–2016–4). Ann Arbor: University of Michigan Transportation Research Institute. Report will be docketed along with this final rule.

[99] *See* Table 2 in UMTRI's report for detailed results. Klinich, K.D., Boyle, K., Orton, N.R., Manary, M.A., & Ebert, S. (2016, January). *Investigation of clearance criterion between tether anchor and head restraint* (Report No. UMTRI–2016–4). Ann Arbor: University of Michigan Transportation Research Institute. Report will be docketed along with this final rule.

lengths of CRS tether hardware.[100] VRTC measured six vehicles with various tether anchorage locations in the rear driver side position and rear center position.

Tether Anchorage Measurements

The VRTC Tether Anchorage Measurement results were similar to those found by UMTRI (*see* Table 2). The six vehicles' seating positions with package shelf tether anchorages failed the proposed 165 mm distance. Only two of those six tether anchorages failed the alternative criterion. Of the two vehicles that failed both criteria, the needed relocation distance of the tether anchorage to meet the criteria was smaller for the alternative criterion than the proposed criterion. All seating positions with the tether anchorage on the seatback or roof passed both criteria.

TABLE 2—VRTC TETHER ANCHORAGE VEHICLE SURVEY RESULTS

Vehicle			Tether location		325 mm zone (mm)	165 mm tether distance (mm)
Year	Make	Model	Rear driver position (RDP)	Rear center position (RCP)		
2010 Ford Taurus			Package Shelf		384	*149*
				Package Shelf	436	*141*
2011 Cadillac CTS			Package Shelf		*294*	*68*
				Package Shelf	409	*74*
2016 Toyota Sienna			Seatback		742	757
				N/A	N/A	N/A
2011 Hyundai Sonata			Package Shelf		*308*	*75*
				Package Shelf	365	*65*
2016 Chevrolet Tahoe			Seatback		625	657
				Seat Back	628	637
2016 Nissan Rogue			Seatback		433	469
				Roof	630	460

VRTC found one of the six vehicles' tether anchorages was off-center for its designated seating position. VRTC used a FARO arm[101] to plot the desired points into a 2D circle diagram. Due to the offset, measurements for that tether anchorage do not correctly capture the depth distance. Therefore, VRTC used a 325 mm sphere (truncated at the bottom) instead of a two-dimensional circle to define the 325 mm zone (*see* figure 4).

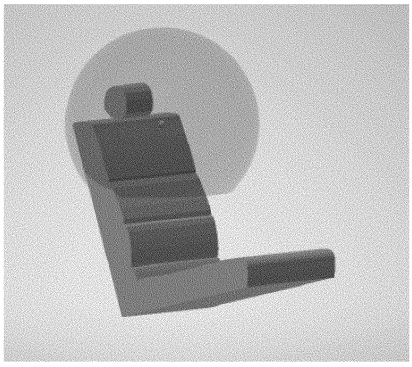


Figure 4. Three-Dimensional 325 mm Zone.

CRS Hardware Measurements

VRTC also measured the tether hardware length of twenty CRSs. The longest tether strap hardware was 190 mm. The shortest was 83 mm. Sixteen of the twenty tether hardware were less than 165 mm in length.

CRS Installation on Vehicles

VRTC completed CRS installations to verify that a vehicle with a 165-mm tether anchorage distance measurement would allow for proper installation of a CRS with a tether hardware length of 165 mm. The CRS selected was an Evenflo Triumph with a tether hardware length of 164 mm. Two vehicles with short distances (close to the 165 mm proposed minimum distance) to the tether anchorage were selected for this portion of the study. The 2010 Ford Taurus (RDP), which had a 149-mm

[100] Wietholter, K., & Smith, J. (2019, November). Evaluation of tether anchor zones for FMVSS No. 225 (Report No. DOT HS 812 842). Washington, DC: National Highway Traffic Safety Administration. Report will be docketed along with this final rule.

[101] A FARO arm is a portable coordinate measuring machine that measures the location of a probe in a 3D space.

tether anchorage distance measurement, was closer to 165 mm than the other selected vehicle. The 2011 Cadillac CTS (RCP) had one of the smaller tether anchorage distance measurements of 74 mm and an odd seat shape. Both the 2010 Ford Taurus (RDP) and 2011 Cadillac CTS (RCP) positions passed the UMTRI alternative criterion based on the 325-millimeter circle centered on the R-point.

Because the 2010 Ford Taurus (RDP) had a tether anchorage distance measurement from the proposed SB point of less than 165 mm, the study anticipated that the tightening of the tether would be difficult. However, the vehicle owner's manual included instructions to install the CRS using the tether attachment by routing it under the head restraint. Since the head restraint was adjustable, no difficulties were experienced when tightening the tether. This result suggests that the tether anchorage distance measurement, defined as the distance from the tether anchorage to the rearmost point on the seat (SB point), does not account for the ease of installation when the head restraint is raised or removed for CRS installation.

Further, since the tether anchorage distance from the SB point for the 2011 Cadillac CTS (RCP) was only 74 mm (significantly lower than the proposed 165 mm), NHTSA expected that the tether would be difficult to tighten when installing a CRS in this seating position. However, installation was not difficult because of the lack of head restraint. Specifically, the seatback cushion in the Cadillac was thick, which allowed enough space between the tether anchorage and the CRS for the tightening of the hardware. For the 2011 Cadillac CTS (RDP), the vehicle owner's manual specified that the CRS tether attachment should be routed over the fixed head restraint, which permitted easy tightening of the tether attachment. If a vehicle with similar spacing had an adjustable head restraint and specified routing under the head restraint in the vehicle owner's manual, it would have been difficult to tighten the tether attachment because the tether attachment hardware would be underneath the head restraint. This finding indicates that ease of installation can be improved with vehicle owner's manual instructions and not just measurement requirements.

Agency Response

After carefully considering comments received and reviewing the results of the UMTRI and VRTC studies, this final rule is implementing a 325 mm radius sphere zone (from R point, with truncation) instead of the NPRM's proposed 165-mm distance from the tether anchorage to the back of the seatback. The decision to adopt the alternative 325 mm zone resolves noted issues in defining the SB point for the 165-mm distance, because the R-point, already defined in the standard, is used in the alternative 325 mm radius sphere zone to define the center of the sphere. Therefore, NHTSA will adopt a 325 mm radius sphere zone (from R-point, with truncation) to define the allowable area for the tether anchorages.

Some commenters, including Honda, Alliance, Ford, and FCA, expressed concern for the expensive tooling costs needed to relocate the tether anchorages. However, the modified requirements adopted by this final rule will minimize or eliminate the number of vehicles that need tooling changes to relocate the tether anchorages, greatly reducing any projected tooling costs.

NHTSA acknowledges Honda's suggestion that the required minimum distance of the tether anchorage should be from a point simulating the attachment of the tether strap on the CRS to the tether anchorage, rather than the SB point. However, the current specifications of the tether anchorage location in FMVSS No. 225 are with respect to the W-point, which is approximately the tether strap attachment point on the CRS. Additionally, this final rule's requirements specify a minimum distance of the tether anchorage with respect to the R-point, which was found to be sufficient for correctly installing and tightening the tether of CRSs. This final rule's adopted approach achieves the goal of improving usability in a practicable manner without imposing design restrictions and undue cost and redesign.

Finally, NHTSA is providing a longer lead time (discussed in detail below) to minimize any costly design changes borne by manufacturers to move tether anchorage locations during the mid-lifecycle of their vehicles.

Comments on Backlight Interference

Several commenters, including FCA, the Alliance, and Hyundai, raised concerns that moving the tether anchorage rearward will likely interfere with the backlight during child restraint tether hook attachment and detachment. FCA noted that the slope of the back glass may need to be changed to alleviate the interference condition. FCA further stated that all of its current tether anchorages are harmonized worldwide and that, if NHTSA mandates relocating the tether anchorage rearward, its vehicles may no longer meet the requirements of ADR34,[102] which governs child restraint anchorages for vehicles sold in Australia. FCA stated that ADR 34.6 requires accessibility to engage an attaching clip and a clearance zone around the tether anchorage. FCA stated that, in the worst-case event, two designs for the package shelf might be necessary, which would increase the overall vehicle cost in all markets. The Alliance stated that the proposed requirement's forced relocation of tether anchorages rearward in the vehicle would result in less hand clearance to the vehicle backlight for attaching and detaching the tether hook.

Agency Response

With this final rule's adoption of the aforementioned changes in determining the allowable tether anchorage zone, any cases where the tether anchorage is pushed back towards the rear window, causing potential conflict with the ADR, will be minimized or eliminated. However, UMTRI's evaluations of the updated measurement showed a small portion of vehicles would still experience conflict based on the requirements of this final rule, so some vehicle designs would have to find alternative locations or design to meet both ADR 34 requirements and FMVSS No. 225 requirements. To the extent doing so is required, the extended lead time and phase-in period provided by this final rule should help to alleviate cost and design burdens to manufacturers.

Comments on Head Restraints and Routing of Tether

The Alliance suggested that the tether anchorage location requirements relative to the back of the seat or head restraint should not apply to vehicle seating positions (1) without a head restraint, (2) with a head restraint that is removed for child restraint installation, or (3) when the vehicle manufacturer specifies that the tether strap is to be routed over or around the head restraint. Similarly, Global commented that the tether anchorage location requirements should not apply to seats having adjustable or removable

[102] Australian Design Rule 34. The stated function of this Australian Design Rule is to specify requirements for ''Child Restraint Anchorages' and 'Child Restraint Anchor Fittings' which provide for the connection of standard 'Attaching Clips' so that 'Child Restraints' may be adequately secured to the vehicle. It specifies a standard package of fitting hardware and accessibility requirements to facilitate correct installation and interchangeability of 'Child Restraints'. *www.infrastructure.gov.au/infrastructure-transport-vehicles/vehicles/vehicle-design-regulation/australian-design-rules/third-edition.* Last accessed November 4, 2024.

head restraints, since such head restraints can be adjusted or removed to allow sufficient space for tether adjustment. Global agreed that the distance criterion might be applied to certain seats having a fixed head restraint, where there is no space between the head restraint and the seat top to enable tightening of the tether strap.

Agency Response

Following careful consideration, this final rule requires vehicles with adjustable/removable head restraints and no head restraints to locate the tether anchorages beyond the 325 mm truncated sphere from the R point to ensure tethers can be easily tightened. The agency disagrees with the Alliance's recommendation that the tether anchorage location requirement behind the seat should not apply to DSPs with no head restraints and removable head restraints. Vehicles in this category could run the risk of having the tether anchorage too close to the CRS, preventing a tight tether installation. While the tether could be routed over the adjustable/removable head restraint, thereby increasing the wraparound distance to the tether anchorage and removing interferences for tightening the tether strap, most manufacturer instructions specify routing the tether strap under the adjustable/removable head restraint. Routing the tether under the head restraint provides the shortest path from the tether anchorage to the CRS, which may have some benefits during a crash (less webbing length results in less stretch). Routing the tether under the head restraint may also offer improved CRS performance in far side impact scenarios as tether routings over the head restraint sometimes slip to the side of the head restraint, allowing for more side excursion. In addition, because some head restraints that protrude or tilt to the front at times interfere with the installation of the CRS, it is typically advised to remove or move the head restraint to a higher position to eliminate this interference. Because adjustable/removable head restraints are likely to be used with a tether routed under the head restraint (for adjustable head restraints), it is important to have the tether anchorage beyond the 325 mm truncated sphere from the R point to ensure tethers can be easily tightened.

In contrast with the Alliance's recommendation, Global suggested that the requirement for the tether anchorage location behind the seat should only apply to DSPs with fixed head restraints. We disagree. As fixed head restraint seating positions do not have any elements that interfere with the installation and tightening of the tether, the agency believes these seating positions should be excluded from the tether anchorage location requirements to ensure there is sufficient space to tighten the tether. Additionally, seating positions with fixed head restraints where the tethers are routed over the restraints increase the wraparound distance from the CRS to the tether anchorages, so they are less likely to prevent tightening of the tether due to limited distance. Finally, there is no interference of the head restraint to route and tighten the tether for seats with fixed head restraints. For these reasons, this final rule excludes DSPs with fixed head restraints from the tether anchorage location requirements.

Comments on Tether Anchorage Location and Pass-Through Door

The Alliance expressed concerns with relocating the center tether anchorage as proposed in the NPRM in relation to a specific design featuring a tether anchorage installed above a luggage compartment pass-through door.[103] The Alliance stated that the proposed minimum wraparound distance would necessitate a tether anchorage position lower on the seatback. The Alliance explained that to accommodate this revised tether anchor position, the size of the pass-through door/opening to the luggage compartment would need to be smaller, thereby significantly limiting its usefulness. The Alliance stated it is not practicable to locate the tether anchorage on the pass-through door because the door lacks the structural strength to meet FMVSS No. 225's tether anchorage strength requirements. The Alliance recommended that the center seating position should thus be exempted from the minimum tether anchorage distance requirement relative to the SB point.

Agency Response

The modified requirements adopted by this final rule will minimize or eliminate the tooling costs that would be necessary to relocate the tether anchorages, and will minimize or eliminate cases where the tether anchorage location could interfere with the position of a pass-through on a center seat (if the tether anchorage cannot be located elsewhere). If a tether anchorage can't be located towards the top of the seat within the new requirements because of a pass-through opening, the tether anchorage could instead be located lower in the seat where a tether strap would go over the pass-through opening area. This scenario would not interfere with the function of the pass-through door because it would not be used when a CRS is installed in the center seating position. As such, the agency is declining to adopt the proposed exemption.

Comments on the Need for Vehicle Manual Information

SRN stated that head restraints present a significant impediment to tethering the CRS in many vehicles and recommended that FMVSS No. 225 require vehicle manuals to provide specific instruction for the proper routing of the tether *vis a vis* the head restraint, along with clear guidance for how to adjust the head restraint to achieve proper routing when necessary. SRN explained that because tethers come in two styles that affect routing (two-point and three-point), instructions should be required to address these differences. SRN also stated that instructions calling for the removal of the head restraint should clarify whether the head restraint can be reattached once the tether is attached, or, if not, where the head restraint should be safely stored. SRN stated that some vehicle owner's manuals have improved these types of instructions over the years, but that this improvement is far from consistent. SRN also stated that in some cases, cargo covers, dog gates, and other accessories supplied by the vehicle manufacturer impede the route of a tether to the tether anchorage. Based on these issues, SRN suggested that the manufacturer be required to provide clear tether routing instructions in the vehicle's manual.

Agency Response

The agency is declining SRN's suggestion to require tether routing instructions in vehicle manuals, as it falls outside scope of the proposed requirements in the NPRM and this rulemaking. NHTSA may consider the addition of instructions for tether routing in vehicle owners' manuals at a later date.

Comments on the Length of the Minimum Distance to the Tether Anchorage and Maximum Length of the Tether Hardware

SRN supported efforts to match up the distance from the child restraint to the tether anchorage and a maximum length of the tether hardware (the hook + adjuster). However, SRN expressed concern that by specifying 6.5 inches as

[103] Shown in figure 16 of the Alliance's submitted comments. Link: *www.regulations.gov/comment/NHTSA–2014–0123–0027*.

both the minimum for the distance from the child restraint to the vehicle's tether anchorage and a maximum for the very shortest tether length, it will continue to be difficult to properly tighten the tether when both the CRS and vehicle meet (but do not exceed) the standard. SRN stated that the minimum distance to the tether anchorage should be at least a half inch (or more) greater than the maximum-allowed fixed length of the tether anchorage for the solution to be effective in all situations (for example, the shortest length for the tether hook and adjuster could be a maximum of 6 inches and the tether anchorage distance no less than 6.5 inches).

Agency Response

SRN commented that having the same 165 mm distance as the requirement to both the tether anchorage distance and the tether hardware length does not ensure proper tightening of the tether, commenting that the minimum distance of the tether anchorage needs to be at least a half inch (or more) greater than the maximum allowed fixed length of the tether hardware for the solution to be effective. As the final rule requirements for tether anchorage location have been modified from those proposed in the NPRM, SRN's suggestion no longer applies to this final rule.

In support of the modifications adopted in this final rule, during the VRTC CRS hardware survey, only 4 of the 20 CRSs had hardware exceeding the 165 mm limit. This finding supports NHTSA's decision to adopt a tether hardware length requirement of 165 mm or less as proposed, as most CRSs already comply with this length. Any changes needed to the tether hardware design in CRSs that currently do not meet this length should not be burdensome, as there are many tether hardware designs available that meet the requirement. Further, this requirement will help address the Alliance and FCA's suggestions to promote CRS uniformity.

Comments on Requiring Tether Anchorages To Be Close to the Proposed 165 mm Requirement

ARCCA commented that NHTSA's assessment of tether anchorage locations appeared to only consider the tether's effectiveness in frontal crashes. ARCCA stated that side impact crashes can result in a similar number of injuries and fatalities as frontal crashes, and that they should be given equal consideration. ARCCA explained that the tether is most effective in frontal crashes, and that a tether also reduces the amount of roll that a forward-facing CRS experiences when the tether length is sufficiently limited. ARCCA added that its own sled testing and quasi-static load testing indicate that the longer the tether, the more the CRS can roll towards the impact during a side impact, and that an increased CRS roll results in increased lateral head excursion. ARCCA explained that this increased head excursion results in increased head impact injuries, the most frequent mechanism of serious injury. For these reasons, ARCCA recommended that tether anchorage locations should be limited to the package shelf and the back of the vehicle seat, and as close to the proposed 165 mm (6.5-inch) minimum as possible. Alternatively, ARCCA recommended that when the distance of the tether anchorage exceeds the 165 mm (6.5-inch) minimum, a tether guide should be provided at the back top of the seatback that has sufficient strength to maintain the tether within the guide during side impact crashes.

Agency Response

This final rule will not reduce the allowable tether anchorage zone to distances close to 165 mm from the SB point as possible, as suggested by ARCCA, because doing so would greatly reduce the allowable tether zone in the standard and may not be feasible in some vehicle designs.

ARCCA's suggested proposal to include a tether guide is not within the scope of this rulemaking, and will thus not be addressed, as it was not proposed in the NPRM and NHTSA does not have any data on tether guides to aid in side impact crashes.

Requests for Clarification

Global requested clarification of the following:

- Which portion of the routing device will be the reference position for the 165-mm distance measurement?
- How much force is to be applied on the strap when making the measurement?

Agency Response

As the agency is not adopting the 165 mm distance from the SB point to the tether anchor, these requested clarifications are moot and need not be addressed, as they do not relate to requirements of this final rule.

2. Tether Hardware Restrictions

To improve compatibility between vehicles and CRSs, NHTSA proposed to amend FMVSS No. 213 to require that the tether hardware assembly (consisting of the tether hook and hardware to tighten and loosen the tether strap) be no longer than 165 mm (6.5 in). NHTSA proposed this limit so that all CRS tether straps can be tightened given the minimum tether anchorage distance from the SB reference point. NHTSA stated that limiting the length of the tether hardware assembly would not be overly burdensome for CRS manufacturers, since the assembly consists of simple parts.

General Comments

The Alliance and FCA opined that the tether anchorage distance and CRS hardware incompatibility is better addressed through the introduction of design rules for the attachment hardware in FMVSS No. 213. The Alliance stated that a survey of 16 child restraints manufactured between 2003 and 2014 found that attachment hardware lengths varied from 120.6 to 171.4 mm (4.75 to 6.75 inches) in length, tether hooks alone varied from 60.3 to 63.5 mm (2.375 to 2.5 inches) in length, and adjuster assemblies varied in both length and circumference (from 120.6 to 196.8 mm (4.75 to 7.75 inches) in circumference). The Alliance stated that the lack of uniformity in CRS attachment hardware and its mounting location on the CRS points to the actual source of the compatibility issue, rather than the vehicle ''swing zone'' behind the seatback or head restraint. Similarly, Hyundai presented a 12 CRS hardware length survey that found a range between 140 to 185 mm (5.5 to 7.3 inches). Hyundai stated that limiting the length of the tether hardware assembly would not be overly burdensome for CRS manufacturers, since that assembly consists of simple parts.

Britax recommended against adopting restrictive dimensional requirements for tether hardware length (165 mm), as it might prevent advancement in tether technologies, and against requiring child restraint manufacturers to modify current tether hardware design. Instead, Britax recommended that child restraint manufacturers simply provide compatible tether hardware as the vehicle tether anchorage dimensions are standardized.

Agency Decision

This final rule adopts a tether hardware length requirement of 165 mm or less as proposed by the NPRM. Most CRSs already comply with this length and changing the tether hardware design in CRSs that currently do not meet this requirement should not be burdensome, as there are many tether hardware designs available that can meet the requirement. Although Britax did not describe how a new tether

technology would not be able to comply with this requirement, any hardware design with a longer distance than 165 mm could prevent tight installations, and therefore, would not comply. Having this requirement will also address the Alliance and FCA's suggestion to promote CRS uniformity.

V-Shaped Tethers

Britax stated it has a patented tether technology which incorporates, in part, a V-shaped tether assembly. Britax stated that the V-shaped tether assembly would meet the proposed tether hardware length requirement. In contrast, UMTRI stated that for V-shaped tethers, the adjustment hardware is typically located a considerable distance from the tether hook, so these tethers may not be able to comply with the proposed requirement. UMTRI also stated that has had had difficulties tightening the V-shaped tether in some Britax CRSs.

Agency Decision

Unlike common tethers that are usually routed directly from the middle of the CRS back to the tether anchorage, a V-shaped tether is routed from the two CRS attachments near the side of the CRS back to the tether anchorage.[104] A V-shaped tether would most likely have a longer distance from each of the back/side attachment points to the tether anchorage and would not have a head restraint interfering during attachment, as it is routed on either side of the head restraint. Factors outside the scope of the proposed requirements on tether anchorage location and tether hardware length may be the cause of difficulties in tightening V-shaped tether anchorages. However, any potential solution is out of scope of this rulemaking and will thus not be addressed by this final rule.

c. Noticing the Tether Anchorages

1. Structures Covering Anchorages

The NPRM proposed to require that a tether anchorage must be in a location where the anchorage is accessible without the need to remove carpet or other vehicle components to access the anchorages. However, the NPRM proposed that a tether anchorage may be covered with a cap, flap, or cover, provided that the cap, flap, or cover is specifically designed to be opened, moved aside, or otherwise provide access to the anchorage. It must also be labeled with the ISO symbol indicating the presence of the tether anchorage underneath. The NPRM also proposed to require the anchorage to be accessible without the use of any tools, including the use of a screwdriver or coin.

Covered Tether Anchorages

Dr. Baer strongly disagreed with the provision allowing for the covering of tether anchorages with any cap/flap/cover, stating concerns that parents do not notice these covers, because vehicle manufacturers do a very good job of making the caps/flaps/covers blend in with their surroundings. Dr. Baer stated that aesthetics of the vehicle need to take a back seat to child safety, and that hiding of the CRAS has directly contributed to the failure of CRAS to reduce misuse rates in the population as a whole since so many parents never find the anchorages in their vehicles.

Agency Response

The agency disagrees that tether anchorage covers should not be allowed. Data from IIHS's study [105] shows that the package shelf is the tether anchorage location most widely used in the field. Tether anchorage covers are most commonly used in package shelf locations and are usually voluntarily labeled with the ISO tether symbol. Although IIHS data does not provide details on whether the tether anchorages in their study had covers or not, data in the IIHS study suggests that it is not detrimental to have a labeled cover on the tether anchorages.

Cargo Covers

The Alliance stated that many SUVs, CUVs, and station wagon-type vehicles are equipped with a luggage compartment cover. The Alliance stated that some of these cover designs must be removed when access to the tether anchorages is required, while others are retracted into their own housing.[106] The Alliance commented that the compartment cover removal does not require any special tools and is, in most cases, conducted with a simple twist, turn, and lift-up movement of the hardware. The Alliance added that in some hatch-back and coupe style vehicles, the package shelf may have to be moved/removed temporarily to facilitate accessing the tether anchorages on the vehicle seatback.[107]

The Alliance provided examples of a hatchback equipped with a lightweight removable security cover hinged near the seatback on one side and tethered to the rear hatch on the other side. The Alliance explained that the cover is designed to be easily removed to transport large cargo when the rear seat is folded flat and that the cover needs to be temporarily lifted or removed to attach the tether to the tether anchorage located on the vehicle structure. The Alliance added that removing the cover is not an impediment to tethering the CRS and the regulation should not prohibit manufacturers from providing the security the covers provide. The Alliance stated that because these compartment covers are easily removable and provide ready access to the anchorages, they do not qualify as vehicle components as provided under the proposed provision.

Global requested clarification on whether luggage room boards or covers that are readily movable to gain access to the tether anchorage are permitted under the proposal, and whether such covers must be labeled.

Agency Response

After careful consideration, this final rule allows cargo covers to be present if they do not need any tools for removal and are marked with a tether marking for each tether anchorage available (*i.e.,* if there are three tether anchorages available under the cargo cover, there should be three tether anchorage markings). As this cargo cover could be removed or relocated away from the actual tether anchorage, the anchorage must also be marked.[108] The agency considered not allowing the cargo cover feature, but the cargo cover is a component that consumers would want to use in most cases to hide the cargo whenever they do not need to access it from the rear seat. Also, because the cargo cover does not have sufficient structural strength to locate the tether anchorage on it, it would not be adequate for installing tether anchorages.

Tether Anchorages Located Under the Fabric With Slit

SRN expressed concerns about some tether anchorages located on vehicle seatbacks and hidden behind the seatback fabric. SRN explained that although a scored slit in the fabric is provided for this design (and in some cases, a tether anchorage marking may

[104] *See* details of attachment to the tether anchorage at *https://us.britax.com/why-britax/innovation/v-shaped-tether.*

[105] Jessica B. Cicchino, J.B., Jermakian, J.S. ''Vehicle Characteristics Associated with LATCH Use and Correct Use in Real-World Child Restraint Installations.'' April 2014.

[106] Illustration can be found on page 14 of Alliance comment submission in Docket No. NHTSA2014–0123–0027. Link: *www.regulations.gov/document/NHTSA-2014-0123-0027.*

[107] Illustration can be found on page 13 of Alliance comment submission in Docket No. NHTSA2014–0123–0027. Link: *www.regulations.gov/document/NHTSA-2014-0123-0027.*

[108] Marking requirements are discussed in a later section of this final rule.

even be nearby), it is consistently difficult for vehicle owners to recognize how to access these type of tether anchorages. SRN explained it is hard to see the slit in low light (such as in a garage) and bewildering to owners that they would be required to perform this step. SRN commented that, because this type of hidden tether anchorage technically could meet the requirements of the proposal, wording should be included in the standard that eliminates this design option and makes exposing the tether anchorage part of the factory assembly procedures.

Agency Response

In response to SRN's expressed concerns, the proposed requirements that ''allow a cap, flap or cover that is specifically designed to be opened, move aside or to otherwise give access to the anchorage'' would not permit such slit access (unless it stays open by itself) because it would not expose the tether anchorage without obstruction. However, in acknowledgement of this concern and to provide greater clarity and avoid any potential confusion, NHTSA is modifying this final rule's regulatory text to ''allow a cap, flap or cover that is specifically designed to be opened, move aside or to otherwise give *unobstructed* access to the anchorage'' to more explicitly rule out slit designs.

Tether Anchorages Under Cargo Floor

Dr. Baer and SRN also commented on tether anchorages located below the level of the cargo floor (*e.g.,* in the Toyota Prius V), explaining that when the second-row seating is rolled back to the regular passenger seating position, the seatback abuts the cargo area floor, and the tether anchorages are completely out of sight and inaccessible. SRN recommended that NHTSA address the problem of tether anchorages that are inaccessible in certain seating locations through an amendment to FMVSS No. 225.

Agency Response

The proposed requirement to have tether anchorages in a location available without the need to remove carpet or other vehicle components to access the anchorages (except for caps, flap or covers designed to provide access to the anchorage) adequately addresses the concerns raised over anchorages positioned below the level of the cargo floor.[109] The agency considers an interfering cargo floor as a vehicle component that is not providing access to the tether anchorage, and therefore not meeting the intent of this requirement. However, as discussed in the previous section, the agency will change the regulatory text to ''otherwise give *unobstructed* access to the anchorage'' to more explicitly rule out slit designs and obstructed anchorages below the cargo floor.

Tether Strap Over Cargo Area

Dr. Baer stated that other tether anchorage locations include the rear wall of the vehicle, which makes it impossible to put cargo in the trunk area with a tether strap crossing over the cargo area. Dr. Baer explained that when forced to decide between using a tether and having room for cargo, most parents will choose the cargo and leave the car seat untethered. Therefore, Dr. Baer disagreed with NHTSA's statement that ''those atypical locations do not appear to pose a safety problem.'' Dr. Baer added that while in the crash test lab a rear wall tether anchorage is fine, in the real world it isn't practical and simply doesn't get used.

Agency Response

Regarding Dr. Baer's comment on not allowing anchorages that interfere with cargo space, this is out of the scope of this rulemaking, as NHTSA did not propose any requirements on this topic or how to evaluate interference with cargo.

2. Elimination of the Option To Use a Tool or Coin To Remove the Anchorage Cover

The NPRM proposed that a tether anchorage must be in a location where the anchorage is accessible without the need to remove carpet or other vehicle components to access the anchorages. NHTSA also proposed the anchorage must be accessible without the use of any tools, including the use of a screwdriver or coin. NHTSA clarified that a tether anchorage may be covered with a cap, flap, or cover, provided that the cap, flap, or cover is specifically designed to be opened, moved aside, or otherwise provide access to the anchorage, and it must also be labeled with the ISO symbol indicting the presence of the tether anchorage underneath.

Comments

Advocates expressed support for improving the regulation regarding better access to tether anchorages, stating that currently tether anchorages must be accessible without the need of any tool except a screwdriver or coin and anchorages are frequently placed in a location requiring consumers to fold back a seat or remove camouflage coverings such as carpet, seat fabric, or a plastic cap. Advocates stated that eliminating the need to use a screwdriver or coin to access a tether anchorage is essential to make CRAS anchorages more user-friendly. Advocates stated that CRAS anchorages intended for use by consumers should be user-friendly, and their location should be readily apparent when needed.

Agency Response

The agency received no comments in opposition to the proposed requirement to require access to the tether anchorages without the use of tools, including a screwdriver and coin. As the agency received comments in support of this proposal and new vehicle models do not have tether anchorages that require a screwdriver or a coin to access them, eliminating this option is feasible, would incur no cost for vehicle manufacturers, and would prevent such designs from coming back into the fleet. As such, the agency is adopting the NPRM's proposal to require access to tether anchorages without the use of tools, including a screwdriver or coin. The agency will also adopt the NPRM's proposed requirement that the tether anchorages must be accessible without the need to remove carpet or other vehicle components to access the anchorage (other than marked caps, flaps, or covers specifically designed to be opened, moved aside, or to otherwise provide unobstructed access to the anchorages). Marked cargo covers will also be allowed as discussed in the previous section.

d. Recognizing the Tether Anchorages

1. Rigid Bar

Currently FMVSS No. 225 does not provide any material or dimensional requirements for tether anchorages, other than specifying that the tether anchorage must permit the attachment of a tether hook meeting the configuration and geometry specified in figure 11 of Standard No. 213. Most vehicle manufacturers use a metal bar design for the tether anchorage. These metal bars vary in cross section shape; some are round, and others are flat. However, a few pickup trucks and MPVs provide a webbing loop as the tether anchorage that can also be used as a router to loop the tether through it and attach to the tether anchorage in an adjacent seat. The webbing loop is so different from the conventional metal bar design that consumers have difficulty identifying them as a router

[109] *See www.cars.com/articles/2014/02/2014-land-rover-range-rover-sport-top-tether-trouble-/.*

and a tether anchorage.[110] Also, in some cases, the webbing anchorages need to be retrieved from another component such as a foldable carpet flap that runs across the back seat. In certain cases, the carpet flap needs to be folded back to find the webbing tether anchorage and then the webbing needs to be pulled out via an object such as a pencil.

To increase the ease-of-use of tether anchorages, NHTSA proposed amending FMVSS No. 225 to standardize the configuration of the tether anchorage such that it is a ''rigid bar of any cross-section shape.'' One of the main objectives of the proposal was to increase the standardization of CRAS features, to increase consumers' familiarity with the anchorage systems, and to increase the ease of using the systems, particularly when coupled with education efforts that provide a simple and uniform message. The NPRM stated its belief that having a standardized design for the tether anchorages such that they can be described as a ''rigid bar'' would help consumers easily recognize the anchorages in their vehicles and facilitate simplified and more effective messages in educational materials.

The NPRM requested comment on whether further standardization of the tether anchorage should be pursued to make the tether anchorage a more recognizable vehicle feature. The agency tentatively decided not to specify dimensions for the tether anchorage to give manufacturers some design flexibility in meeting FMVSS No. 225's strength requirements.

General Comments

Three commenters (UMTRI, Advocates, and Dr. Baer) supported the standardization of the tether anchorages to a rigid bar. UMTRI specifically supported prohibiting the use of webbing as a vehicle tether anchorage. Advocates commented that standardizing the tether anchorage will allow consumers to identify the device and understand its intended use more easily. Global supported NHTSA's approach in not specifying the dimensions of tether anchorages, as this would provide manufacturers design flexibility in meeting FMVSS No. 225 strength requirements. Some commenters, including CR, GM, the Alliance, FCA, and Global, expressed concern regarding eliminating the flexible anchorages in certain vehicles. These concerns will be discussed in detail in the following sections.

The Alliance stated that because the NPRM included the proposed requirement for marking all tether anchorages with standardized symbols, any further standardization is not necessary to make the anchorages more recognizable. The Alliance further stated that there is no data to substantiate that the proposed requirements standardizing the configuration of the tether anchorages will increase consumers' familiarity with the anchorage systems and will increase the ease of using the systems, aside from facilitating simplified messages in educational materials.

Agency Response

After careful consideration and review of comments received, NHTSA is adopting the proposed requirements for tether anchorages designs to be a ''rigid bar of any cross-section shape.'' However, this final rule allows for some exceptions to this provision, which are discussed in detail below.

2. Flexible Tether Anchorages for Pickup Trucks Versus Foldable Seats

Pickup Trucks

FCA commented that several proposed requirements within the NPRM present technical feasibility concerns for pick-up trucks, as the inherent architecture of a pick-up truck is such that the seats are located near the rear of the occupant compartment with a glass window directly behind the seat.[111] FCA explained that taken together, the proposals of the rigid bar requirement for tether anchorages, accessibility without folding the seatback, and the minimum distance of 165 mm from the reference point ''SB,'' make the technical feasibility of the design solution even more complex in pickup trucks, going against the goal of the NPRM. FCA also stated that the tentative design solutions to meet all the requirements proposed in the NPRM would not increase usability of tether anchorage and would add unnecessary cost and weight to the vehicles.

The Alliance stated that to meet the proposed requirements (rigid tether anchorage, no folding of seat to access the tether anchorage, and the minimum distance of 165 mm from the reference point ''SB'' to the tether anchorage), manufacturers would have to include seat tracks so that they can move the seat forward (instead of folding) to allow access to the tether anchorage. Alliance added that currently the standard allows for designs that provide a folding seat in the rear row of a pickup to provide access to the tether anchorages.

GM stated it uses flexible tether anchorages made with steel cable in conjunction with routers on many of its pickup truck models. GM and the Alliance explained that the need to use routers will increase if access to the tether anchor is no longer permitted by folding the seatback.

Agency Response

After reviewing comments received regarding the standardization of the tether anchorages as a rigid bar and the requirement for tether anchorages to be accessible without folding the seat, the agency believes flexible tether anchorages should be allowed in some types of vehicles. The agency acknowledges that permitting flexible tether anchorages in some vehicle types will not achieve the proposed standardization of tether anchorages, but believes the design challenges associated with adding tether anchorages on pickup trucks and other vehicles where the tether anchorage cannot be installed within the tether ''allowable zone'' in the required standard merits allowing these vehicles the option of having flexible tether anchorages (that can also be used as routing devices).

Using Flexible Tether Anchorages With Routers Versus Accessing Tether Anchorages Behind Seatback

CR expressed concern about the elimination of the adjacent routing option for tethers in pickup trucks. CR acknowledged that the adjacent loop method of attaching the tethers in pickup trucks is different and less intuitive than in most other vehicles; however, CR stated that based on evaluations of tether anchorage access in pickups prior to the availability of the adjacent routing technique, it was still a preferable alternative to some of the more hidden tether anchorage locations behind a folding seatback. CR stated these alternate locations create a unique imbalance when installing a forward-facing seat between holding the seat and accessing the tether anchorage.

Similarly, GM relayed feedback it received from child passenger safety technicians (CPST) regarding the flexible cable tether anchorage versus rigid anchorage located behind a folding seatback. Feedback received stated that while it may take some familiarity or consultation with the owner's manual,

[110] Klinich, K.D., Manary, M.A., Malik, L.A., Flannagan, C.A.C. ''Tether Anchors in Pickup Trucks: Assessing Usability, Labeling, and Performance'' November 2016. *https://deepblue.lib.umich.edu/bitstream/handle/2027.42/156027/UMTRI-2016-30.pdf?sequence=1&isAllowed=y.*

[111] Illustration can be found on page 10 of FCA's Appendix A submission in Docket No. NHTSA2014–0123–0025. Link: *www.regulations.gov/document/NHTSA-2014-0123-0025.*

once a user understands how to route and attach the tether using the flexible routers it is easier to do than it is to fold the seat forward to access a rigid anchorage on the back of the seat or cab wall, attach the tether, fold the seatback upright, and then install the CRS and tighten the tether strap. GM opined that it is no more complicated or confusing to attach the tether hook to a flexible cable-type anchorage than to a separate rigid anchorage in situations where use of a router is required.

FCA [112] submitted current designs with webbing straps, located behind each seating position, that serve as both the tether strap routing device and the tether anchorage. FCA explained that when a child restraint is installed in a seating position, the tether strap for the child restraint is routed through the routing device behind the seating position in which the child restraint is installed and the tether hook is then attached to the strap in the adjacent seating position. FCA stated that it provides clear installation instructions in the owner's manual to explain the correct child restraint installation procedure and that due to the flexibility of the strap on the vehicle, it is quite easy to attach the tether hook to the tether anchorage. FCA pointed out that due to the proposed NPRM requirement that the tether anchorage be a rigid bar, this design will no longer be allowed.

Agency Response

Following careful consideration of comments received, NHTSA agrees with CU, GM, and FCA that flexible tether anchorages that can also be used as routers are easier to use than tether anchorages located behind a folding seatback. While the tethering method of looping the tether strap through the routing device and attaching it to a tether anchorage (also a routing device) of an adjacent seating position is not intuitive at first, once the method is known it is easily understood and easily performed. Therefore, flexible tether anchorages will continue to be allowed in some vehicles.

Request To Allow Folding Seat To Access Tether Anchorage

Global requested that the agency allow the folding of seatbacks to access the tether anchorage in pickup trucks where no practical alternative exists to locate the tether anchorage.

The Alliance stated that packaging space in single row vehicles (discussed in the next section) and in pickup trucks is often limited and seats are often located near the rear of the occupant compartment. The Alliance added that locations for tether anchorages are regulated in the current FMVSS No. 225 and need to have suitable vehicle structure to manage the forces of the child restraint in a crash. The Alliance elaborated that one solution often found in sports coupes and pickup trucks is to locate the tether anchorage on the vehicle body where loads can be managed, behind the passenger seat.[113] The Alliance stated that access to the anchorage requires the seat to be moved or tilted forward to attach the tether hook to the anchorage and that once the hook is engaged, the seatback is moved backward to a locked position and the tether strap is tightened. The Alliance explained that, as currently proposed in the NPRM, the tether anchorages would likely need to be relocated to the vehicle's body and that the relocated anchorage would require the addition of a tether routing loop behind the head restraint.

Agency Response

The agency has decided not to allow seats to be folded to reach the tether anchorages in pickup trucks because it is more difficult to install a CRS using this method, as it may require an iterative installation process to achieve the desired tight installation. Pickup truck designs that require the vehicle seatback to be folded to access the tether anchorages can be modified to include flexible tether anchorages (that can be used as routing devices). Some of these pickup designs may already have enough structure to handle the tether loads if changed to a flexible tether anchorage design, although some may have to be reinforced.

Based on comments and inspections performed by the agency, pickup trucks that do not use the flexible tether anchor/routing device have a foldable seatback that allows access to a rigid tether anchorage in the seatback in the back wall or floor of the pickup. Additionally, in some pickup trucks, depending on the design of the CRS tether hardware, the hardware can prevent the seatback from latching, which could cause consumers to not use the tether at all.

While the agency acknowledges Global and the Alliance's comments that some pickup trucks should be permitted to have folding rear seats to access anchorages, as no practical alternative exists to locate them, we respectfully disagree with this view. Although certain pickup trucks may require some modifications to meet the requirements of this final rule, pickup trucks that have folding rear seats should be able to accommodate the routing/tether anchorage design. Further, this design should not interfere with vehicle models that have moving or foldable backs to access other elements such as storage or tools.

Reduced Rear Seat Space if Other Solutions Are Not Allowed

FCA stated that because the NPRM proposal does not allow for flexible tether anchorages and folding the seatback to access the tether anchorage space behind the seat, accessible tether anchorages would come at the expense of passenger space in the rear seat to meet the proposed requirements. FCA stated that reducing the space behind the front seat is counterproductive to the overall goal of fitting children in child restraints in the back seat of vehicles, including pickup trucks.

Agency Response

Since this final rule permits flexible anchorages and routers, manufacturers should not have to choose to include seat tracks to move the seat forward or to reduce the rear seat space to access the tether anchorage without folding the seatback. We agree that reducing the rear seat space to create an accessible tether anchorage would be counterproductive to helping fit CRSs in the rear seat.

Conflicts With FMVSS No. 202

FCA stated that other regulations such as FMVSS No. 202a can be in direct conflict with the changes proposed in the NPRM because they can impede the access to the tether anchorage even further.[114] FCA stated the proposed rigid bar requirement for tether anchorages, accessibility without folding the seatback, and the minimum distance of 165 mm from the reference point SB make the technical feasibility of the design solution even more complex, as the head restraint would block access to the rigid tether anchorage and the head restraint could not be folded, as the folding the seatback is assumed to not be allowed.

Agency Response

Continuing to allow the flexible anchorage with router design should

[112] Illustration can be found on page 13 of FCA's Appendix A submission in Docket No. NHTSA 2014–0123–0025. Link: *www.regulations.gov/document/NHTSA-2014-0123-0025.*

[113] Illustration can be found on page 11 of Alliance comment submission in Docket No. NHTSA2014–0123–0027. Link: *www.regulations.gov/document/NHTSA-2014-0123-0027.*

[114] Illustration can be found on page 12 of FCA's Appendix A submission in Docket No. NHTSA2014–0123–0025. Link: *www.regulations.gov/document/NHTSA-2014-0123-0025.*

eliminate the concerns expressed by FCA in relation to any potential conflict with the new tether location requirements (*see* section above VI.b.1), the restriction of folding the seatback to access the tether anchorage, and having to place the tether anchorages in locations that will allow tightening of the tether. The cost to implement the routing device/tether anchorage designs should be low, as most pickup trucks already have such designs. Further, per this final rule, flexible anchorages and routers will be allowed in vehicles where no part of the shaded tether anchorage zone in the standard is accessible without folding the seat or removing a seating component of the vehicle (per S6.2.1.1 of FMVSS No. 225). Head restraints will also be allowed to be moved/folded or removed to provide better access to the anchorages.

Conflicts With Canadian Standard

The Alliance stated that if NHTSA revised S6.2(b)(1) as proposed it would create a dilemma if CMVSS 210.1 is not similarly revised, since most or all manufacturers of these vehicles also sell these vehicles in Canada.

Agency Response

The requirements adopted by this final rule continue to allow flexible tether anchorages with routers for vehicles that cannot locate the tether anchorage in the ''allowed zone.'' Therefore, these requirements do not conflict with Canada's standard.

Labeling Instead of Vehicle Modifications

The Alliance recommended NHTSA require a label on the top/side of the seatback (facing toward the door) directing consumers to the presence of the tether anchorage behind the seatback to prevent costly vehicle modifications. The Alliance stated that this requirement would allow tether anchorages to remain in relatively accessible and expected locations in these vehicles.

Agency Response

NHTSA disagrees with the Alliance's suggestion to require a label on the seatback to direct consumers to the tether anchorage behind the seatback, as such a label would not solve the difficulties in tightening the tether when it is located behind the seat, or the inability to re-latch the seatback due to interference with certain CRS tether hardware. NHTSA also does not have information on the effectiveness of such a label, and it falls outside the scope of this rulemaking.

3. Single Row Vehicles

FCA stated that packaging space in single row vehicles is very limited, with seats often located near the rear of the occupant compartment. FCA explained that because the location for the tether anchorage needs to have a suitable structure to manage the forces in a collision, tether anchorages are often located on the structure behind the passenger seat. FCA added that access to such tether anchorage requires the seatback to be moved or tilted forward to attach the tether hook to the tether anchorage, and that once the hook is engaged, the seat is returned to its normal driving position and the tether strap is tightened.[115]

FCA described two of its single row vehicles, the Dodge Viper, and the Alpha 4C, which require the user to fold the front passenger seatback forward to gain access to the tether anchorage located on the vehicle structure directly behind the passenger seat. FCA stated there are limited engineering solutions available capable of withstanding the forces required by FMVSS No. 225 in both vehicles, and recommended NHTSA continue to allow the folding of the seatback to gain access to tether anchorages installed in single row vehicles.

Agency Response

NHTSA disagrees with FCA's expressed concern regarding access of tether anchorages for single row vehicles and this final rule will not permit the folding of the seatback to access the tether anchorage. Pickup trucks also have a challenging geometry and have been able to accommodate tether anchorages with routing devices. NHTSA acknowledges single row vehicles face similar challenges where no part of the shaded tether anchorage zone in the standard is accessible without removing a seating component of the vehicle or folding the seat-back forward. However, as discussed earlier in this section, vehicles with these characteristics will be allowed to accommodate routing devices to avoid folding the seatback to access the tether anchorages. CRS installation is easier using routing devices for attaching the tether-to-tether anchorages than CRS installation involving folding the seatback to access the tether anchorage, because such an installation would be an iterative process for tightening the tether or, depending on the CRS tether hardware design, could create a condition where the seatback cannot be re-latched, resulting in consumers not using the tether at all. As previously stated, this final rule will permit flexible anchorages and routers in vehicles where no part of the shaded tether anchorage zone in the standard is accessible without folding the seat or removing a seating component of the vehicle. Further, head restraints will be allowed to be moved/folded or removed to provide better access to the anchorages. This allowance should alleviate the aforementioned concerns raised by FCA.

4. Buses With a GVWR of 10,000 Pounds or Less

GM requested that buses under 10,000 pounds gross vehicle weight (*i.e.,* 12 and 15 passenger vans) be exempt from the requirement that the tether anchorages be a rigid bar. GM pointed out that school buses are already exempt altogether from requirements to provide any tether anchorages. GM explained that the 12–15 passenger van segment is a very small (much less than 1 percent of total market sales) specialized segment of vehicles which are typically driven by employees or individuals affiliated with a business or organization. GM provided figure 5 below showing the metal anchorage in these vehicles is attached to a flexible strap which is bolted to the lower seat structure. GM also noted that the seats in these vehicles have a single seatback shared by 3 or 4 seating positions and that these seats are already quite heavy and would become even heavier if additional structures were added to it to handle CRS tether loading. GM explained that today, as marked, these anchorages are readily recognizable and easy to use. GM recommended allowing flexible strap tether anchorages for bus applications.

[115] Illustration can be found on page 9 of FCA's Appendix A submission in Docket No. NHTSA2014–0123–0025. Link: *www.regulations.gov/document/NHTSA-2014-0123-0025.*

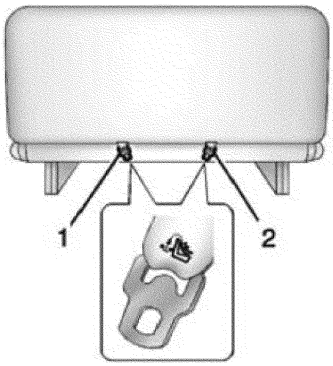


Figure 5. Chevrolet Express Tether Anchorage

Agency Response

NHTSA agrees that there is merit to GM's request to permit flexible tether anchorages on buses with a gross vehicle weight of 10,000 pounds or less. Requiring rigid anchorages in these types of vehicles may increase the weight of the vehicle when adding structures for the rigid anchorages. This is an important concern as vehicles are only required to provide 3 tether anchorages, and added weight might deter manufacturers from continuing to provide additional tether anchorages in these types of vehicles. The agency will therefore exclude buses with a GVWR of 10,000 pounds or less from the requirement for rigid tether anchorages.

VII. Conspicuity and Identification of Vehicle Anchorages and CRS Connectors

NHTSA proposed to amend FMVSS No. 225 to require all vehicles to bear the ISO standardized markings developed by ISO's voluntary standard near all lower anchorages and tether anchorages provided in the vehicle to improve the ease with which consumers find lower anchorages and tether anchorages in the vehicle. The agency also proposed requiring the same ISO markings on CRS lower anchorage connectors and on tether hooks. The agency proposed that the lower anchorage connector marks must be at least 9 mm (0.35 in) in diameter. Further, the NPRM proposed that the markings on the tether anchorage connector must be on the tether strap or a tag attached to the strap, and that the marking must be located within one inch of the tether hardware assembly (tether hook and adjustment hardware). The proposal also stipulated that the tether anchorage connector markings must be at least 8 mm (0.35 in) in height.

NHTSA also proposed that both vehicle and CRS manufacturers must include an explanation of the meaning of the markings in the vehicle manual to make consumers more aware of the existence of CRASs and to facilitate consumer education efforts by simplifying education messages. Currently, the ISO voluntary standard has two different tether anchorage symbols and under the agency's proposal CRS manufacturers and vehicle manufacturers would have the option of using either marking.

a. General Comments and Agency Responses

1. General Support for Markings and Manuals Requirements for Vehicle and CRSs

Several commenters expressed support for the proposed standardized ISO markings on all child restraint anchorages and the child restraint anchorage connectors. Two commenters, IIHS and Dorel, also stated they supported the proposed language requirements for the vehicle and child restraints manuals. IIHS and Dr. Baer agreed that the standardized symbols and presence of markings will help simplify educational messaging to parents.

Britax commented that consumers are reluctant to review vehicle owner's manuals to determine tether anchorage locations and that they have witnessed consumers attaching the tether to non-tether anchorage points. Britax further stated that making vehicle tether anchorages more visible and consistently marked should improve and encourage tether usage. Similarly, Advocates stated that a common error in properly installing a CRS is the attachment of the tether to a device that is in fact not a tether anchorage. Advocates explained that requiring a standard symbol at the location of each tether anchorage, regardless of whether the anchorage is visible, will assist consumers in not only properly installing a CRS but increasing awareness of the existence of these devices. Advocates commented that instituting uniformity in markings by requiring a standard symbol already used by the International Standardization Organization (ISO) and adopted by a majority of vehicle manufacturers will further assist consumers in identifying both the lower anchorages and tether anchorages.

Agency Response

Following review of comments received, the agency has decided to adopt the proposed lower anchorage and tether anchorage markings, as well as the proposed markings for CRS lower anchorage connectors and tethers. The agency received widespread support for the markings, although some commenters had concerns with the restrictive locations of the markings with respect to the anchorages, the symbols required, and some vehicles that have specific challenges such as pickups and hatchbacks that may have an open trunk. The following section further discusses the issues raised by the commenters regarding the proposed requirements for anchorage marking location and design, NHTSA's decision on the issues, and the final rule requirements.

2. Marking Contrast and Color Coding

IIHS and Dr. Baer supported the proposed improved labeling to identify tether anchorages but stated that a color contrast requirement for the label should be incorporated in the standard. IIHS stated that labeling itself was not associated with tether use in its study,[116] explaining that this result may be because the embossed labels that are

[116] Jermakian J.S., Klinich K.D., Orton N.R., Flannagan C.A.C., Manary M.A., Malik L.A., Narayanaswamy P. 2014. Factors affecting tether use and correct use in child restraint installations. *J Safety Res* 51:99–108.

frequently used are often difficult to see. Similarly, SRN and Dr. Baer stated that some tether anchorage markings currently in vehicles are extremely difficult to see, even in daylight conditions, because the marks are engraved into dark plastic. SRN stated that the tether anchorage markings will only accomplish the intended goal if they are easily visible.

Advocates stated that during the 2007 public meeting they urged NHTSA to require all tethers anchorages and lower anchorages to be conspicuously marked. Advocates added that the 2006 Decina study, *supra,* revealed that the majority of consumers who did not use lower anchorages (55 percent) reported that they did not use them partly because they could not find them or did not know where they were located in the vehicle. Advocates stated that while it would be optimal to have all persons who install add-on CRSs be fully acquainted with the FMVSS No. 225 CRAS, a portion (if not a majority) of the public will not be fully conversant and informed regarding the CRAS. Advocates stated that requiring anchorages and connectors that are color-coded or otherwise conspicuous, and that obviously match the CRS anchorages or connectors, is one way to provide intuitive cues that can lead to increased rates of proper installation even among those members of the public who are not fully conversant with technical details and requirements of FMVSS No. 225. Dr. Baer supported the markings on CRS lower connectors and tethers but suggested that vehicle and CRS manufacturers should be required to use a specific color on the symbol to help parents match the colors in addition to the symbol.

Graco requested clarification on (1) whether the proposed marking on the CRS lower anchorage and tether anchorage connectors can be embossed or engraved (*i.e.,* molded in plastic or stamped in steel), (2) whether the required markings can, but do not have to be, color contrasting, (3) whether the pictogram for lower anchorages can be on a tag or if it must be in the connector, and (4) whether the pictogram on figure 16 in the NPRM is permitted on an attached tag that is located 25 mm, measured from the shortest distance from the nearest edge of the pictogram, to the tether hardware. Dorel agreed that if the marking is on the tether strap or a tag attached to the strap, the marking must be located within one inch of the tether hardware assembly (tether hook and adjustment hardware).

Agency Response

NHTSA acknowledges the suggestion raised by several commenters that the proposed vehicle markings should have contrast or even color coding. However, the agency is declining to include color coding requirements in the markings for this final rule, as this specific issue is outside of the scope of this final rule since the NPRM did not propose any color contrast or color coding on the markings. Further, NHTSA does not have data on the incremental benefit of having contrast and/or color coding in the markings; this determination would require evaluation of whether contrast/color markings result in more correct installations than markings without color contrast. However, NHTSA encourages manufacturers to make the markings as visible as possible, including via contrast and/or color to further improve the usability of the equipment. Similarly, the CRS connectors will not be required, but will be allowed, to have color contrast.

For the markings on the CRS connectors, Graco requested clarification on whether the proposed marking on the CRS lower anchorage and tether anchorage connectors may be embossed or engraved (*i.e.,* molded in plastic or stamped in steel). The proposed FMVSS No. 225 does not have any requirements on how the marking is fabricated; therefore, molded plastic, stamped in steel, and other methods are allowed as long as the location and size of the required marking requirements are met. As certain methods of marking could be applied to webbing, manufacturers are reminded that component requirements of FMVSS No. 213, *e.g.,* webbing breaking strength,[117] are subject to compliance testing with the marking included, if it is present on the sample to be tested.

Further, although the proposal did not explicitly permit the lower anchorage connector mark to be on a tag, the option of having the marking on the connector itself or a tag located 25 mm (similar to the proposal for the tether anchorage connector tag) from the connector is beneficial, as some connectors (hook-type) may have more difficulties accommodating the symbol. As such, in response to Graco's comment, NHTSA is permitting the pictogram to be located on a tag that is 25 mm from the connector. This measurement will be made from the nearest part of the connector (plastic/metal part not webbing) to the tag with the tether symbol.

b. Lower Anchorage Marking Comments and Agency Responses

1. Lower Anchorages I-Size, ISOFIX and Other Text in Symbols

MEMA urged NHTSA to consider allowing the use of other existing marking designs used in ISOFIX and i-Size labels (figure 6), which are widely used in the industry in many markets. MEMA explained that consistency of markings is critical for its global company members that supply to global vehicle manufacturers. MEMA added that the small differences between the agency's proposed markings and those already in use would result in redesigning and changing component production to feature the different symbols, which adds cost and burden for manufacturers.

MEMA added that, depending on the overall design, the surrounding shape of the symbol may not always take the form of a circle or sphere. Although the agency did not propose any changes to the marking shape language in the current standard, MEMA suggested the agency consider permitting other shapes to enclose the symbol as the United Nations Economic Commission for Europe (ECE) regulations do permit ISO or iSize symbols/labels. Similarly, the Alliance stated that parts of ECE Regulation 44[118] are incorporated into the new UN R–129[119] with new size and functional performance criteria, and that the new CRS will be marked as i-size-ready. The Alliance explained that in order to guarantee the fitment of these CRSs in the vehicle, original equipment manufacturers must fulfill requirements in addition to those currently in ECE R14 and R16. The Alliance added that if seating positions fulfill the new i-Size option of ECE R14 and R16, they may be marked as an ''i-Size seating position'' with the i-size-symbol (square) replacing the ISO-symbol (round). MEMA urged NHTSA to clarify the marking location to allow the symbol to appear within other shapes, and to consider harmonization with ECE label requirements.

[117] FMVSS No. 209, S5.1.

[118] ECE R.44, ''Restraining devices for child occupants of power driven vehicles (Child restraint systems),'' *www.unece.org/fileadmin/DAM/trans/main/wp29/wp29regs/2015/r44r3e.pdf.*

[119] ECE R.129, ''Uniform provisions concerning the approval of enhanced child restraint systems used on board vehicles (ECRS),'' *www.unece.org/fileadmin/DAM/trans/main/wp29/wp29regs/2013/R129e.pdf.*

Figure 6. ISO and i-Size Symbols

MEMA added that NHTSA's proposed language appears to only allow for the use of a single symbol as depicted in the NPRM, which is a much narrower requirement than the current regulation that allows for words, symbols, and pictograms. MEMA raises this issue because the ISO standard symbol, in some cases, may include the term ''ISOFIX'' or ''i'' near the symbol. MEMA urged NHTSA to allow text to be either inside or adjacent to the ISO standard pictogram symbol (indicating such allowances in the notes associated with the attributed figure/symbol) and to consider harmonization with ECE label requirements.

The Alliance stated that one element of the i-Size option in European regulation (ECE R14 and R16) is the support leg installation assessment. The Alliance relayed that some rear-facing infant child restraints have introduced this feature and more, (including forward-facing restraints) may follow as the newly proposed FMVSS No. 213 side impact requirements [120] become effective. The Alliance stated that vehicle manufacturers have already received questions regarding the use of these types of seats for installation purposes and that a vehicle manufacturer could potentially indicate, with the placement of the new square symbol, that its floor design will uphold use of a support leg.

The Alliance added that when comparing both ISO and i-Size symbols, the i-Size symbol could even encourage the user to check the owner's manual since ''I,'' in general ISO terms, is the symbol for ''information.'' The Alliance suggested that as long as the symbol's meaning is explained in the owner's manual, either the ISO or i-Size symbols should be permitted to identify the lower anchorages in the vehicle.

Agency Response

MEMA and the Alliance requested allowing both the ''i-size'' marking and the ISO lower anchorage marking, as they are very similar (instead of a circle, the ''i-size'' marking is a rounded square and has a letter ''i'' in the marking), and that doing so would help harmonization efforts. The Alliance stated that if the vehicle had an ''i-size'' symbol the consumer would be able to recognize vehicles where they can use CRSs with support legs or that the ''i'' could be used as an ''information'' icon so that the consumer looks in the vehicle's manual.

Following careful consideration, this final rule does not allow for the use of the i-size marking. Since ''i-size'' requirements are not in U.S. standards, the U.S. cannot verify that anchorages marked with the ''i-size'' symbol meet the corresponding European ''i-size'' requirements. This means that NHTSA could not ensure that the vehicle would accommodate a CRS with a support leg. Further, the agency could not ensure that vehicle manufacturers would consistently use an ''i-size'' symbol only when vehicles do meet the European ''i-size'' requirements. NHTSA is also not persuaded that the ''i'' in ''i-size'' could be used as an information icon, which would be inconsistent with the meaning of ''i-size''.

This final rule does allow the term ''ISOFIX'' to be displayed near, but not instead of, the new required symbol. This is because the ISOFIX standard is more aligned with U.S. standards and the term has been used for the lower anchorages in the U.S. market for many years.

2. Lower Anchorage Markings Tolerances

MEMA stated that adding markings to visible lower anchorages may require trim design changes and redesign to meet the proposed requirements. MEMA commented that seat designs with a visible lower anchorage would not be able to accommodate a marking placed in the existing 50 mm zone. MEMA explained that because some seat designs have trim seams running vertically through the 50 mm zone, the button markings are offset from the seams, making it challenging to have the marking within the compliance zone.

MEMA added that other designs have the seat-cushion bight line within the marking zone, making it difficult to package the marking and meet the proposed dimensional capability. MEMA stated that the industry solution for this difficulty has been to make the lower anchorage wire visible.

MEMA stated the proposed requirement to add markings to visible lower anchorages may not have a safety implication, but might have a quality implication on the trim. Thus, MEMA urged NHTSA to reconsider the need to mark visible lower anchorage wires. In the alternative, at minimum, MEMA requested that NHTSA expand the compliance zone dimensions to accommodate seat trim design elements. MEMA recommended increasing the lower anchorages' vertical zone to 25 to 125 mm and the horizontal zone to ±50 mm from the centerline of the wire. MEMA stated that these increased tolerances will help marking visibility, keep the marking within compliance, and avoid potential redesign of seating function/design elements. MEMA also requested clarification on S9.5(a) of the current regulation, which reads: ''Above each bar installed pursuant to S4, the vehicle shall be permanently marked with a circle.'' MEMA asked for clarification on the ''above,'' as there are cases where the latch wires are positioned higher than at the seat bight, meaning that the label may not be situated above the latch wire, but in front of it.

SRN agreed with the proposals related to the ability to identify anchorages and recommended a requirement that the lower anchorage markings be placed on the vehicle seatback cushion in an area above the lower anchorages. SRN explained that this recommendation would allow for consistent usage verbiage to describe searching below the mark. SRN added that although nearly all current markings comply with this suggestion, there are exceptions in which the marking is placed below the lower anchorage bar on the vehicle seat cushion.

Agency Response

The agency disagrees that markings should not be required for visible anchorages, which would not accomplish the standardization the agency is seeking. The current standard allows for the marking of the lower anchorages to be on a tag, and

[120] The proposed FMVSS No. 213 side impact protection was later adopted as FMVSS No. 213a-Side Impact Protection.

manufacturers could use this method if vertical seams do not allow for the positioning of a button-type marking centered ±25 mm with the anchorage. The agency also disagrees with the suggestion that the standard should increase the allowable vertical zone for the marking from 50–100 mm to 25–125 mm and the horizontal zone from +100 mm (forward) to ±50 mm. Specifically, a 25 mm (vertical) distance above the lower anchorages may be too small, as the contour of the seat may position the marking downwards, making it difficult for a customer to see. Additionally, a 125 mm distance may be too far away from the lower anchorage to be able to identify the correct equipment. However, NHTSA does agree that the horizontal zone should be expanded to accommodate seat contours where the marking would be positioned behind the anchorage when a visible anchorage is more forward. Therefore, NHTSA is expanding the allowable horizontal zone for marking from +100 to −50 mm (*see* figure 7) for this final rule.

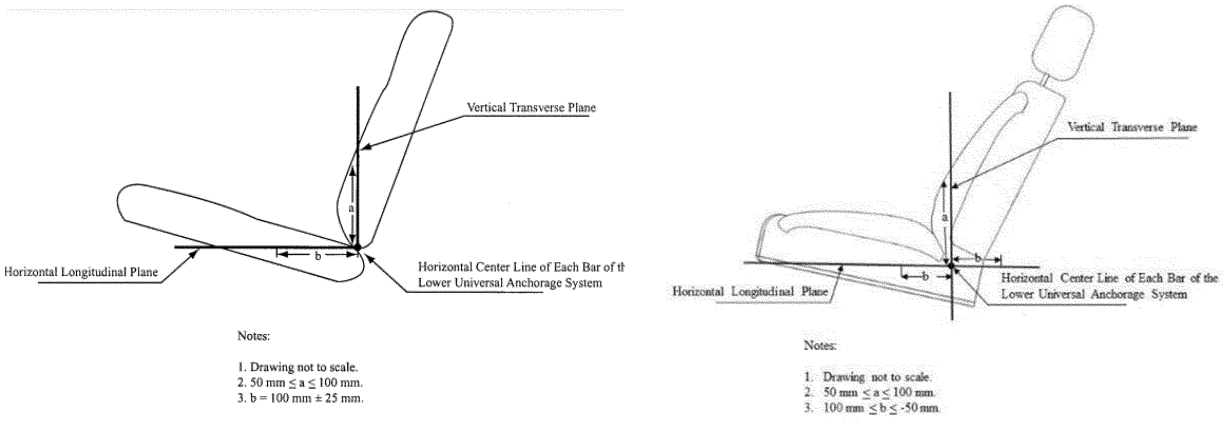


Figure 7. FMVSS No. 225 Figure 22 (left) and Updated FMVSS No. 225 Figure 22 (right)

Given the additional lead time provided by this final rule, manufacturers should be able to make any necessary adjustments to their trim design to enable them to always have the lower anchorage marking above the lower anchorage in all vehicles, whether they are visible or not.

In response to the request for clarification on S9.5.1(a), NHTSA agrees that the word ''above'' could cause confusion, as S9.5(a)(3) specifies the allowable location of the marking which can be above, or in front of, the lower anchorage. Therefore, this final rule will delete the word ''Above'' from section S9.5.1(a) to avoid any confusion.

In response to the comment that the lower anchorages' markings should be placed above the lower anchorages based on SRN's finding that while most vehicles have the marking above, some manufacturers place it below the lower anchorage bar, NHTSA points out that the current FMVSS No. 225 requires the marking to be on the seatback area between 50 and 100 mm above the anchorage or on the seat cushion 100 ±25 mm forward, as illustrated in figure 22 of FMVSS No. 225 (which will be slightly changed to accommodate visible lower anchorages in this final rule). The marking also must be centered with the center of the bar (±25 mm). Given differences in seat, anchorage, and seat designs, we believe having the marking centered with the anchorages along the seatback or seat cushion is sufficient to identify the lower anchorage. Additionally, as the agency did not propose removing the already allowed area for the marking on the seat cushion, additional restrictions on this area would be outside the scope of this rulemaking.

3. Lower Anchorage Tag With Weight Limit

Britax suggested that the agency consider requiring ''acknowledgment'' of the load limits of the lower anchorages with a flag tag or vehicle seat label consistent with the recent revisions to FMVSS No. 213, which restricts use of the lower anchorages to the child weight limit of 29.5 kg (65 lb) minus the CRS weight. Britax explained that currently this weight restriction is indicated on labels on the child restraint, but that also providing lower anchorage flag tags or vehicle seat labels instructing the consumer to check their vehicle owner's manual would reduce the opportunity for misuse and remind consumers that the use of lower anchorages is weight limited.

Agency Response

NHTSA does not believe requiring a label with a weight limit identified on the lower anchorage markings will help consumers or promote ease-of-use, as the child weight limit required on the CRS label is specific to each CRS. Therefore, vehicle manufacturers cannot calculate the child weight limit specific to each CRS to use with the lower anchorages to install a CRS. In fact, a label on the lower anchorages with the combined allowable weight of the CRS and child could confuse the consumer, because they would have to determine the CRS weight, calculate the allowable child weight, and then compare it to the CRS label, which may not match in many cases. As such, this final rule will not require a label with a weight limit identified on the lower anchorage markings.

4. Tether Anchorage and Connector Marking Size Height vs. Diameter

MEMA commented that the reference to the figure 25 pictogram in the NPRM indicated that the tether anchorage cannot be less than 20 mm in diameter, but pointed out that the figure itself actually shows a height of 20 mm, rather than a diameter. MEMA expressed concern that the 20 mm diameter on the tether anchorage may not include the entire pictogram for some applications (depending on the function/design of the tether anchorage component); therefore, MEMA urged NHTSA to revise the regulatory text to refer to a height, rather than a diameter.

Similarly, Global, GM, and the Alliance stated that given the manner in which the pictogram measurement is shown in figure 25 of the proposed

regulatory text, along with the irregular shape of the pictogram, the 20 mm criterion can more appropriately be described as ''height,'' rather than ''diameter.'' Finally, the Alliance stated that the ''circle'' referred to in the last line of 9.5.2(b) means a ''symbol'' in figure 25, and should be referenced as such in the regulatory text.

Agency Response

NHTSA agrees with the aforementioned comments expressing concerns over the reference to the diameter, rather than the height, in relation to figure 25 of the NPRM, and is correcting the proposed regulatory text in response to these comments. As such, this final rule will state that the tether anchorage marking cannot be less than 20 mm in height. NHTSA also agrees with the Alliance's statement that the ''circle'' referred to in the last line of 9.5.2(b) means a ''symbol'' in figure 25 of the NPRM, and this final rule will reference the marking as a symbol instead of a circle for clarification purposes.

c. Tether Anchorage and Connector Marking Comments and Agency Responses

Tether Anchorage and Connector ISO Symbols

In response to the proposal to use either of the two ISO symbols to mark child restraint tether anchorages and connectors, Dorel commented that with the introduction of CRASs it adopted the same standardized ISO symbol marking of child restraint anchorage connectors to harmonize and improve the ease-of-use of CRASs. Dorel added that child restraint manufacturers would have the option of using either marking. The Alliance stated that either of two ISO labeling tether symbols may be used.

In contrast, SRN and UMTRI stated it would be better to choose a single ISO tether anchorage symbol to mark the tether anchorages and connectors to reduce any confusion that may arise from the different symbols. SRN stated it was unaware of the original reason for ISO developing two similar symbols or whether having two symbols serves an ongoing purpose. SRN also stated that the two designs do not have a purposeful difference.

Agency Response

The agency received comments in support of and in opposition to standardizing the two tether anchorage markings currently available in the ISO standard (figure 8). NHTSA believes the symbols are sufficiently similar for consumers to recognize either of them; therefore, the agency will allow either ISO symbol to be used, rather than selecting only one permitted symbol for use. Although the agency has not done an analysis on whether one symbol is more easily understood by consumers than the other, given the extremely similar nature of the symbols, the agency believes either symbol will provide sufficient identification for ease-of-access for consumers.

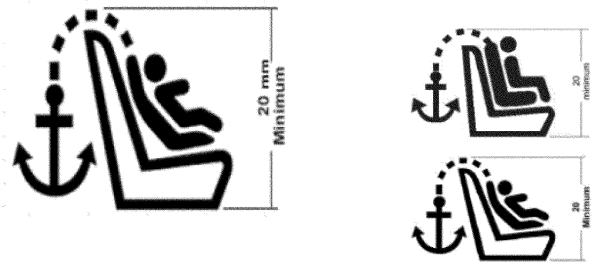


Figure 8. NPRM Regulatory Text Figures 25 (left) and 16 (right): ISO Tether Symbols

d. Tether Anchorage Marking Comments and Agency Responses

1. Whether the Tether Anchorage and Tether Anchorage Cover Marking Location Is Too Restrictive

The Alliance, MEMA, and Global expressed several concerns regarding the NPRM's proposed requirements on the tether anchorage and tether anchorage cover marking location. The Alliance did not support the proposed requirement to locate the tether anchorage symbol a distance no farther than 25 mm from the center of the anchorage for uncovered anchorages. The Alliance stated that NHTSA provided no explanation for the basis of selecting 25 mm for tether anchorage labeling. The Alliance further stated that markings for tether anchorages in current vehicles can be located much farther away at either 50–100 mm above or 25–100 mm in front of the anchorage bars while still being easily recognizable.[121] The Alliance pointed out that some current vehicles that have easily recognizable anchorage markings would not meet the proposed marking requirements.

The Alliance explained that for these vehicles the distance from the anchorage bar to the edge of the recess well is 35 mm, and the distance to the symbol is 38 mm. As such, to meet the maximum proposed 25 mm distance, the clearance provided by the plastic bezel would need to be shortened by 13 to 22 mm, making it more difficult for consumers to attach and detach the tether hook. The Alliance stated that this requirement would reduce ease-of-use, producing the exact opposite effect that the NPRM is attempting to accomplish.

The Alliance also requested clarification on how ring style tether anchorages[122] would be handled under the proposed requirements. The Alliance stated that type of anchorage is well marked, but where the tether hook attaches to the anchorage is 38 mm from the symbol. The Alliance added that to meet the 25 mm requirement, the size of the ring would need to be decreased to 25 mm and that such a modification is unnecessary and would make the anchorage less easy to use.

Similarly, MEMA stated that the 25 mm distance is too constrained for current standard production components. MEMA explained that, depending on the functional design size

[121] As illustrated in figure 17 of the Alliance comments in Docket No. NHTSA–2014–0123–0027. Link: *www.regulations.gov/comment/NHTSA-2014-0123-0027*.

[122] As illustrated in figure 18 of the Alliance comments in Docket No. NHTSA–2014–0123–0027. Link: *www.regulations.gov/comment/NHTSA-2014-0123-0027*.

of the component piece that surrounds the tether bar, such a tolerance could place the mark either on the edges or in the interior of the bar and its surrounding component. MEMA added that not only is it difficult to achieve such a marking (under typical molding and manufacturing processes), but that it could also potentially obscure the marking and impact visibility, thus defeating the agency's goal to improve conspicuity. Further, MEMA commented that the proposed 25 mm dimension tolerance may force redesign of tether hook components, which could impact the surrounding opening of the tether bar, thus making attachment of the tether hook more difficult. MEMA explained that under that scenario, NHTSA's goal to improve usability would be defeated; therefore, to properly mark the component containing the tether bar/hook attachment without forcing redesign of the component fascia or function, MEMA urged NHTSA to increase the compliance marking zone dimension to at least 50 mm.

The Alliance stated that the proposed requirement to have the center of the symbol aligned with the center of the anchorage length to a tolerance of ±5 mm is unnecessarily restrictive. The Alliance explained that a 5 mm tolerance from the centerline is either not practicable, given current seat labeling and construction manufacturing processes, or unnecessary to achieve the agency's stated goal. In making these statements the Alliance referenced its comments and petitions for reconsideration to the original CRAS rulemaking, documenting practicability limitations.[123] The Alliance recommended that the tolerance for tether anchorage markings be ±25 mm, consistent with the requirements for lower anchorage markings.

The Alliance also commented that for some designs it is very difficult or impossible to include a tether anchorage marking that complies with the proposed requirements in section 9.5.2.[124] The Alliance explained that some tether anchorages have recessed plastics from which the anchorage protrudes and that although the mark does not fall within 25 mm of the center of the anchorages, those tether anchorages' marks are clear and visible to the consumer. The Alliance suggested that tether anchorage marking locations be allowed in both the longitudinal and lateral directions from the anchorage. Similarly, Global explained that in some cases there may be no practical location meeting the centerline and 25 mm anchorage bar-pictogram distance criteria. Global urged the agency to establish less stringent criteria to allow for variations in vehicle interior architecture. Global also explained that the more detailed specification could be impractical for some vehicle designs, and stated that manufacturers have every incentive to ensure that the pictogram is located in a manner that is not confusing to consumers.

Agency Response

Regarding the location of the tether anchorages markings, we agree that the proposed distance from the anchorages to the symbol is too restrictive and that in some cases it could make the tether anchorage shorter while also making it more difficult to use. NHTSA also acknowledges comments presenting examples of markings that were more than 25 mm away from the anchorage while still clearly identifying the tether anchorage as such. In response to these comments, NHTSA agrees that a distance of 100 mm is reasonable; however, the agency will also require that no other anchorage (cargo tie down or similar) or structure that could be confused with an anchorage be closer to the tether anchorage marking than the corresponding tether anchorage (figure 9). This requirement will ensure that the markings clearly identify the corresponding tether anchorages, while giving manufacturers more flexibility to position the markings. NHTSA believes that 100 mm is a reasonable distance, as it is still within the current lower anchorage location marking distance range.

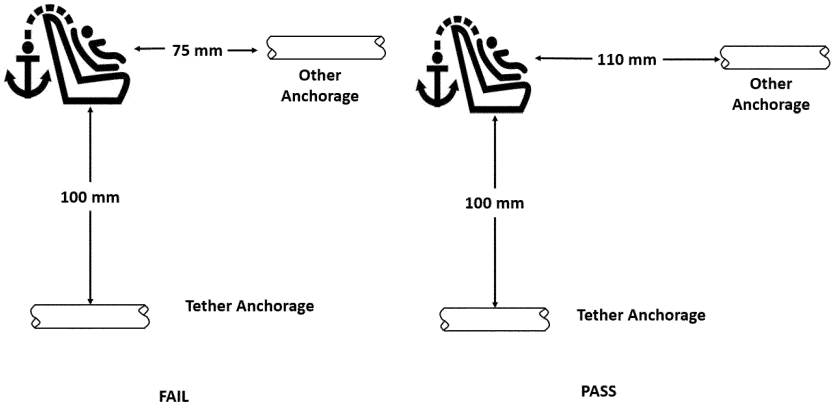


Figure 9. Revised Distance of Tether Anchorage Marking from Tether Anchorage.

Further, NHTSA acknowledges comments made by the Alliance and MEMA relating to the restrictive tolerances proposed for the centering of tether anchorage markings with a ±5 mm tolerance; however, we disagree with the suggestion of a ±25 mm tolerance. Unlike lower anchorages, tether anchorages do not have a required minimum length of 25 mm. Therefore, as some tether anchorages can be quite narrow in design, a ±25 mm tolerance would allow a marking located completely to the side of the tether anchorage, which may cause confusion.

[123] June 2, 2000, NHTSA–1999–6160–0022 (p3–5), August 11, 2003, NHTSA–2003–15438–0005 (p3–4), and March 24, 2004, NHTSA–2003–15438–0011 (p2 and attachments C and D).

[124] As illustrated in figure 19 of the Alliance comments in Docket No. NHTSA–2014–0123–0027. Link: *www.regulations.gov/comment/NHTSA-2014-0123-0027*.

This final rule will instead have the tether anchorage marking centerline intersect the tether anchorage along the tether anchorage's length (figure 10). This requirement will ensure that the tether anchorage marking centerline crosses the length of the tether anchorage. It will also give the manufacturer the flexibility to choose an anchorage width and a tether symbol size that suits their manufacturing needs.

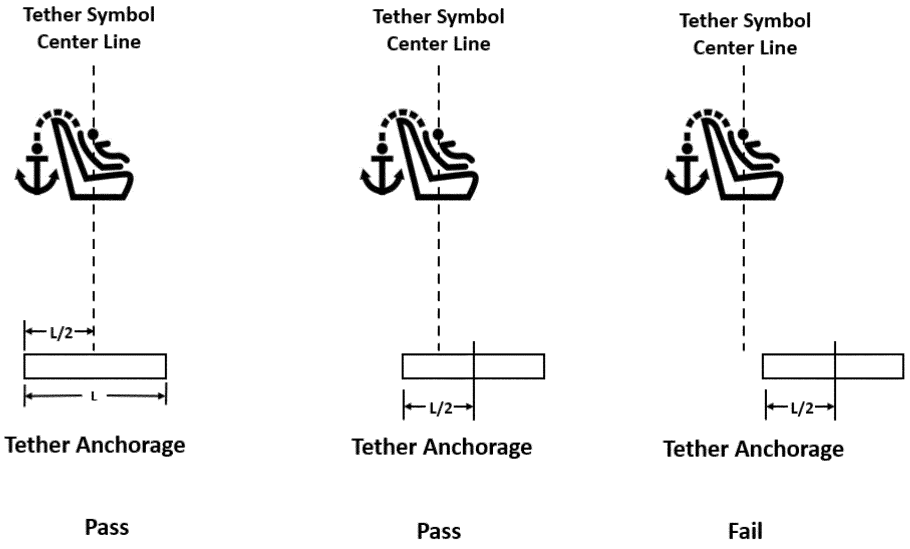


Figure 10. Tether Symbol Centered to Tether Anchorage (vertically)

The agency also agrees with the Alliance that in some cases it would be difficult to align the tether anchorage marking to the width of the tether anchorage. However, NHTSA would like to keep some consistency on the location of the markings to easily guide the consumer to the tether anchorage. Therefore, NHTSA will also allow locating the tether anchorage marking to the sides of the anchorage. Per this final rule's requirements, half of the height of the marking must overlap/intersect the tether anchorage, as shown below in figure 11. Manufacturers may choose a larger symbol size (with a minimum height of 20 mm) that gives them the flexibility to meet this requirement.

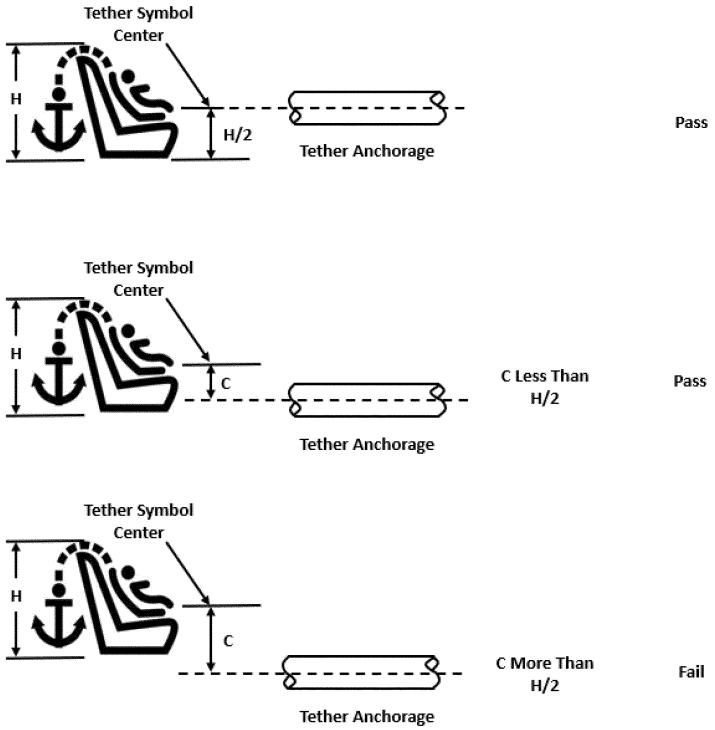


Figure 11. Tether Anchorage Symbol Centered to Tether Anchorage (horizontally)

Finally, the agency agrees with comments stating that the NPRM's proposed alignment and tolerances of the marking on the tether anchorage cover would create an unnecessarily restrictive and impractical requirement, as consumers will still understand that what is under the cover is a tether anchorage even without these rigid requirements. Such manufacturing precision would thus be an unnecessary and increased burden on manufacturers. As such, this final rule will still require the proposed marking on the tether anchorage cover but will not specify the alignment and tolerances of the marking location.

3. Tether Anchorage Markings in Cargo Covers

As discussed earlier in this final rule, NHTSA will allow the presence of cargo covers as long as they do not need any tools for removal. In addition to the markings by the tether anchorages, cargo covers will have to be marked with a tether symbol for each tether anchorage available below the cargo cover.

There will be no requirements on the location of the marking on the cargo cover, as the location of the cargo cover with respect to the anchorage is varied. Manufacturers should indicate in their instruction manuals how to access the tether anchorages. Tether anchorages under the cargo cover will also need to be marked with the ISO symbols adopted in this standard.

2. Tether Anchorage Markings for Routing Devices

Global suggested that FMVSS No. 225 should require a separate label for tether routing devices to assist consumers in proper routing of the tether strap. Global further suggested that a different symbol than the proposed tether anchorage symbol should be used for tether routing devices to avoid consumer confusion.

The Alliance stated that given the proposed requirements for rigid anchorages in pickups for use in conjunction with routers, it is unclear whether the marking requirements can be met. The Alliance stated that the location of the marking may not be visible or help consumers readily identify and locate the correct tether anchorage for the corresponding seating position. Similarly, Global suggested a separate label for tether routing devices and/or use of a different tether symbol to avoid consumer confusion.

Agency Response

NHTSA disagrees with comments suggesting that FMVSS No. 225 should require a separate label for tether routing devices to assist consumers in proper routing of the tether strap and disagrees that a different symbol than the proposed tether anchorage symbol should be used to avoid consumer confusion. Specifically, we disagree that there is a need to provide a different label and symbol for pickup trucks, as part of the effort of this rulemaking is to standardize markings and features to help develop simple educational efforts. NHTSA has reached this decision after careful consideration of comments received and the findings of a UMTRI research study,[125] which showed that using different labeling strategies to identify and guide users to the tether anchorages had no effect on tether use, attaching the tether to the correct anchorage, or correct tether use. NHTSA does recognize the unique aspects of pickup trucks, and believes that standardizing tether markings, paired with instructions in user manuals and education outreach efforts, will help improve current levels of correct tether use.

In response to concerns regarding difficulty meeting the proposed marking requirements for rigid anchorages in pickup trucks in conjunction with routers in pickup trucks, as discussed previously, this final rule allows for the use of flexible tether anchorages that may also be used as routers.

NHTSA also recognizes that tether anchorages in pickup trucks may not be visible unless the consumer looks for them behind the head restraint. Notwithstanding this issue, the agency believes the tether markings required by this final rule are warranted both for standardization purposes and consumer awareness. However, given the expressed concerns over the unique designs of some pickup trucks, if a marking cannot be positioned within the allowed distances of this final rule, NHTSA will permit its placement on the flexible routing/tether anchorage device with a tag, or for the marking to be positioned within 100 mm of the anchorage.

4. Differences in the NPRM's Tether Symbol in Tether Anchorage Marking Location (No Cover and With Cover) Figures and the ISO Symbol

MEMA and the Alliance stated that figures 26 and 27 referenced in the proposed regulatory text (figure 12) depict a different pictogram than the proposed ISO Tether Symbol inside a label and that the pictogram is not referenced elsewhere. MEMA requested clarification on this issue and asked that NHTSA use consistent pictograms in all of its figures in the regulation.

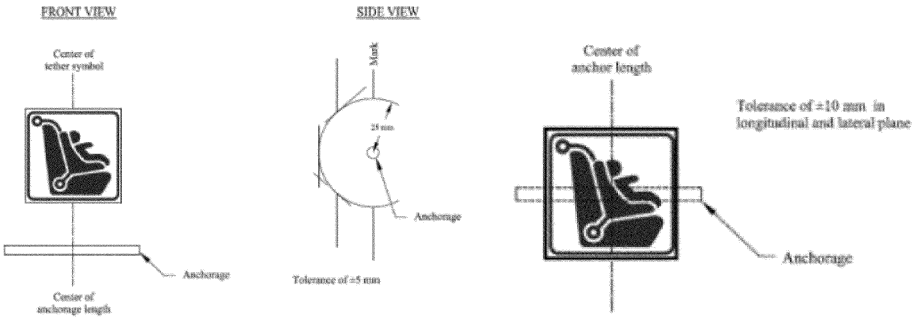


Figure 12. NPRM Figures 26 (left and center) and 27 (right): Tether Anchorage Marking Locations with No Cover and Cover Respectively.

[125] Klinich, Kathleen D., Manary, Miriam A., Malik, Laura M., Flannagan, Carol A.C. ''*Tether Anchors in Pickup Trucks: Assessing Usability, Labeling and performance*''. UMTRI–2016–30. November 2016. *https://deepblue.lib.umich.edu/bitstream/handle/2027.42/156027/UMTRI-2016-30.pdf?sequence=1&isAllowed=y.*

Agency Response

The agency is making changes to the pictograms so that they match the ISO standardized markings to avoid any confusion.

VIII. Applying FMVSS No. 225 to Vehicles Currently Excluded From FMVSS No. 225

The 2015 NPRM requested comments on the feasibility of installing tether anchorages in convertibles, as FMVSS No. 225 currently excludes convertibles from having to provide tether anchorages in rear seating positions (see S5(a) of FMVSS No. 225). The NPRM proposed deleting the tether anchorage exclusion for convertible vehicles because several convertible model vehicles have demonstrated that they can accommodate them. Specifically, the agency found that among 35 convertible vehicle models from the 2013 vehicle fleet, 10 were equipped with the full CRAS (lower anchorages and tether anchorage) in two rear DSPs, 14 were equipped with only the lower anchorages at two rear DSPs, and 11 were not equipped with any anchorages.

NHTSA also requested comment on whether the exclusion of lower anchorages in rear designated seating positions where interference with the transmission and/or suspension components prevent the location of the CRAS lower anchorages anywhere within specified zones (S5(e) of FMVSS No. 225) is still needed. NHTSA explained that manufacturers have gained experience in designing and installing vehicle seats with lower anchorages since the issuance of FMVSS No. 225. The 2015 NPRM tentatively determined there is no longer a need for S5(e) and proposed deleting it. NHTSA requested comment on why the technical problems that existed at the time of the implementation of the final rule in 1997 could not be overcome by the knowledge gained since 1997 and on the feasibility of installing tether anchorages in the second row of convertibles, and in the first row in convertibles that do not have a second row.

Comments

Several commenters supported removing the exclusion of CRASs on convertibles, with some pointing out that manufacturers have had many years of experience installing CRASs in vehicles and should now have the experience to overcome obstacles in installing tether anchorages in these vehicles. UMTRI stated that the challenge of implementing tether hardware in pickup trucks is no greater than what would be required for convertible vehicles, and that the innovations and designs that have been developed to allow tether anchorages in pickup trucks should be sufficient to guide methods to implement tether hardware in convertibles.

Dr. Baer commented that if the exemption for convertible vehicles does continue, convertibles should be required to state that forward-facing children may not ride in the positions lacking tether anchorages. Dr. Baer further stated that the tether anchorage is of greater importance in vehicles with minimal head excursion room, as most convertibles have far less than the 32 inches in their back seats.[126] Dr. Baer stated that exempting these vehicles leaves children at risk, as parents continue to put forward-facing children in these back seats, and that because most rear-facing CRSs cannot fit in a convertible, children placed in car seats in the back are most likely in a forward-facing seat. Advocates stated that the elimination of this exemption will serve as an important incentive to meet current safety standards for manufacturers that do not offer rear tether anchorages in convertibles.

The Alliance and Porsche supported continued exemption for convertibles. The Alliance explained that some vehicle manufacturers may have addressed certain technical problems (such as deployable head restraints) by placing the tether anchorages on the vehicle seatback or the vehicle structure behind the passenger seat.[127] However, the Alliance pointed out that the proposed FMVSS No. 225 S6.1(b) will no longer allow for this type of solution, because the vehicle seatback would have to be unlatched and moved forward to access the top tethers. Therefore, the Alliance recommended continued exemption for convertible vehicles from the installation requirements for tether anchorages.

The Alliance and Porsche also opposed removing S5(e) from FMVSS No. 225 on the grounds that the same issues that existed when S5(e) was created may exist today or in the future; specifically, space limitations or transmission/suspension part interference issues may prevent lower anchorages from being located in the zone described by S9.2 or S15.1.2.2(b) so that the attitude angles of S15.1.2.2(a) cannot be met. The Alliance and Porsche also stated that S5(e) should be retained to maintain harmonization with ECE Regulation 14.

Agency Response

After careful consideration of comments received, this final rule will remove the exception provided for convertibles in S5(a) for the lower anchorages. NHTSA disagrees with commenters suggesting that the NPRM's proposed prohibition on moving the vehicle seat to reach the tether anchorages would make it impossible for some convertibles to have a tether anchorage. Specifically, convertible vehicles could incorporate a tether router/anchorage to accommodate this requirement through a method similar to that used by pickup trucks,[128] which, like many of these currently excluded vehicles, have a back wall instead of a package shelf or trunk space that would give more options for installing the tether anchorages. Further, in response to comments that the lower anchorage exception in (S5(e)) should not be removed because the same challenges that existed at the time of implementation still exist today, NHTSA has observed that some of these vehicles have already been redesigned to accommodate anchorages despite existing challenges. For example, the Porsche 911 Carrera already includes the implementation of the lower anchorages in newer designs. While the agency acknowledges that changes might be required for some vehicles to accommodate the lower anchorages, industry has already shown that it is possible to do it in ways that would comply with this final rule.

However, taking into consideration comments received and in acknowledgement that changes required to meet this final rule may include redesign of convertibles and/or vehicles with a rear designated seating position for which interference with transmission and/or suspension components prevents the location of the lower bars of the child restraint anchorage system in the allowable zones, this final rule will provide a 6-year lead to provide manufacturers enough time to accommodate any necessary changes.

[126] It is the agency's understanding that Dr. Baer is referencing the 32-inch head excursion limit allowed in FMVSS No. 213 when CRSs are tested without a tether attached.

[127] *See* figure 25 of Alliance Comments Link: *www.regulations.gov/comment/NHTSA-2014-0123-0027.*

[128] An earlier section of this final rule discusses how, contrary to the NPRM's proposal, NHTSA will still allow flexible tether anchorages and routers as a solution for pickups, single row vehicles and buses.

IX. Public Responses to Request for Comments and NHTSA's Views

a. Center Rear Seat—Dedicated, Shared, or No Lower Anchorages

Currently FMVSS No. 225 (S4.4) requires vehicles with three or more forward-facing rear DSPs to have a CRAS at no fewer than two of the rear DSPs. Vehicles with three or more forward-facing rear DSPs must currently have a tether anchorage at a third forward-facing DSP. At least one tether anchorage must be in a forward-facing rear DSP other than an outboard DSP (*i.e.,* a center seat). The March 5, 1999, final rule (64 FR 10803) acknowledged that vehicle manufacturers would likely install the lower anchorages in the two outboard seating positions as two CRAS were unlikely to fit side-by-side in the rear seat. Thus, the requirement for a third tether anchorage at a center seat provides consumers the option to install child restraints in a center DSP, where there is the vehicle's belt system and a tether anchorage. Vehicle surveys of applicable MY 2010–2011conducted by NHTSA and UMTRI revealed that of vehicles with a rear center DSP, none offered two dedicated lower anchorages in the center position.

Since the issuance of the 1999 final rule, many consumers have expressed a desire to use the rear center seating location to install a CRS using the lower anchorages. In response to these requests, NHTSA's 2015 NPRM sought comment on possible ways to address this issue, suggesting and seeking comment on the following approaches:

(1) *Require a set of lower anchorages in the rear center seating position, instead of one or both of the CRASs available at the outboard positions in most current vehicle models.* We requested comment on the feasibility of installing a CRAS in a rear center seating position and on whether we should require such installation.

(2) *Require a third set of dedicated lower anchorages in the rear center seat.* The agency requested comment on the feasibility of installing a dedicated CRAS in the rear center seating position in addition to the two-anchorage system in the outboard seating positions in vehicles with 710 mm (27.9 in) or more distance between the centerlines of outboard lower anchorages.

(3) *Require a simulated CRAS.* We requested comment on whether the standard should require a simulated CRAS in the rear center seating position consisting of the inboard lower anchorages of the CRAS in the two outboard seating positions and the center seat tether anchorage.

Comments

Dedicated, Shared, or No Lower Anchorages in Center Seat

IIHS, SRN and Global supported the ability to use center lower anchorages (simulated or dedicated) but indicated that the decision to provide dedicated anchorages or to allow simulated ones should be left up to the vehicle manufacturer. IIHS and SRN explained that vehicle manufacturers are in the best position to determine the solution that works best in each vehicle, and that requiring dedicated anchorages in all three second-row seats, where available, may increase confusion and the likelihood for misuse if lower anchorage sets overlap and it is not clear which anchorage pairs are intended for each seat position. SRN also suggested that CRS manufacturers should be required to address simulated CRASs in their instruction manuals and be encouraged to test for this usage so that it can be permitted, whenever possible, with their CRSs that have flexible lower anchorage straps.

Similarly, Global stated that the decision on how to provide center lower anchorages should be left to the manufacturer to avoid limiting design flexibility and interior layout. Global commented that for smaller sized vehicles with two rows, the current CRAS requirements are adequate for rear seating positions. Global added that if anchorages for a rear center seating position were required it would not allow a rear seat fold-down design that splits at the middle (50 percent centerline), as there would be interference with an installed rear center CRS.

SRN stated that parents concerned with safety often wish to put their child in the center seating position. SRN further stated that many sources indicate that the center seating position is the safer location (including American Academy of Pediatrics (AAP) and many CRS manufacturer websites), supported by at least one major study showing it to be 43 percent safer than an outboard position.[129] SRN indicated support for the options to use lower anchorages in the center, as it is something many caregivers want. SRN explained that many caregivers install the CRS in the center seat using what NHTSA calls a simulated system, but in circumstances in which doing so is not allowed by one or both manufacturers (CRS and vehicle). SRN added that since the majority of caregivers do not get assistance from a CPST, they are often surprised when told they may not do use a simulated system because the installation would otherwise appear to be correct (sufficiently tight). SRN further stated that some caregivers are upset when they realize they cannot use the lower anchorages in the preferred center position, especially when it is their impression that an installation is safer when using the lower anchorages, so they feel they are in a no-win situation. Finally, SRN stated that the seat belt in the center is not always easy to use for installing a CRS and does not always provide an adequately tight installation.

UMTRI, CR, and Advocates supported the addition of a dedicated third set of lower anchorages to the center position of rear seats when there is space available, and a simulated lower anchorages installation allowance for vehicles with insufficient space to fit a dedicated set of lower anchorages. CR supported increased education from manufacturers to allow a simulated lower anchorage installation for flexible lower anchorage straps on wider lower anchorages.[130] CR added that standardized spacing is still necessary for the smaller population of CRSs equipped with rigid attachments but stated that the recommendation to use simulated/non-standard spacing would help installation success for the larger number of seats equipped with flexible lower anchorage straps.

UMTRI stated that the frequency of having three children in a single row using CRS is low; however, having center and outboard seating positions equipped with (or allowed to use) lower anchorages provides flexibility and options, so parents traveling with one child can use the safest center position, but can use both outboard positions if CRSs are too large to be installed in adjacent seating positions.

UMTRI suggested that testing on nonstandard spacing of lower anchorages using CRSs with both push-on and hook-on connectors be conducted. UMTRI explained that since the majority of tests run to evaluate the effects of non-standard spacing have been run with hook-on connectors, a more diverse data set might reassure CRS manufacturers that non-standard spacing is acceptable across a variety of products.

Advocates indicated that they have been a proponent of equipping the rear

[129] Kallan MJ, Durbin DR, Arbogast KB. ''Seating patterns and corresponding risk of injury among 0- to 3-year-old children in child safety seats'' Pediatrics. 2008 May;121(5):e1342–7. doi: 10.1542/peds.2007–1512. PMID: 18450877.

[130] CR relayed that only two manufacturers consistently allow use of the inboard anchorages for center lower anchorage installation in their owner's manuals, if the practice is also allowed by the CRS manufacturer.

center seating position with lower anchorages for many years since the CRAS was proposed in 1997. Advocates added that they also urged NHTSA to require full CRS anchorage systems in all center seats during the 2007 public meeting. Advocates explained that current (FMVSS No. 225) requirements have generally resulted in consumers installing CRSs with the CRAS in the outboard seating positions when the center rear seating positions did not have the lower anchorages available, but that many consumers have expressed a desire to place a CRS in the rear center seat.

Advocates stated that many other child passenger safety authorities have also long recommended that when a child is transported the safest location is the center rear seating position. Advocates explained that placing the child in the rear seat moves the child away from safety concerns associated with travel in the front passenger seat and that locating the CRS in the rear center position keeps children away from doors and windows and potential intrusion in the event of a side impact crash. For this reason, Advocates stated that NHTSA's not addressing the need for a CRAS in the center rear seat in the initial 1999 final rule, and in the intervening 15 years, has been difficult to understand.

Advocates added that a 2009–2010 survey conducted by Safe Kids revealed approximately a third of children restrained by a CRS ride in the rear center seat. Advocates stated the desire to seat young children in CRSs in the rear center seating position should not be new information to the NHTSA, as the agency itself, along with many passenger and vehicle safety organizations, had been recommending the use of the rear center seating position as the optimal location from a safety standpoint for a single CRS for many years, even before concerns about airbag interactions with young children seated in the front passenger seating position became known. Advocates also referenced a December 2014 study performed for NHTSA by UMTRI that found that the majority (56 percent) of 2010–2011 MY vehicles included in the survey could support a dedicated set of lower anchorages in the rear center seat.[131]

Ford stated that the UMTRI conclusion that seats with 710 mm (27.9 inch) or more distance between the centerlines of outboard lower anchorages would have sufficient space to provide three sets of usable dedicated lower anchorages in the right, center, and left seating positions in the rear row does not consider spacing issues related to seatbacks that fold down. Ford stated it has found a high customer expectation for folding seatbacks due to the cargo carrying flexibility they offer, and now offers this feature on nearly all its passenger cars and SUVs. Ford commented that some parents want to place children in the center position using child restraint anchorages and that it has evaluated different alternatives to address consumers' desires. Ford stated that large vehicles may be able to provide an additional pair of lower anchorages in the center position; however, this option is not feasible on most seats due to packaging of seat belt hardware and seatback pivot mechanisms.

Ford agreed with NHTSA's conclusion that use of lower anchorages spaced wider than 280 mm is acceptable in most vehicles, provided the child restraint can be installed securely, and the child restraint manufacturer permits this installation. Ford stated that it has found loads applied to lower simulated anchorages spaced 520 mm apart are comparable to loading of anchorages spaced 280 mm apart. Since the anchorages are already tested using the SFAD2, Ford expressed its belief that additional testing would be redundant. Ford stated that in recognition that some seat designs may preclude secure installation, it has included the following owner manual notices, which provide clear direction to a care giver using lower anchorages at the center seating position.:

- Depending on where you secure a child restraint, and depending on the child restraint design, you may block access to certain safety belt buckle assemblies and LATCH lower anchors, rendering those features potentially unusable. To avoid risk of injury, occupants should only use seating positions where they are able to be properly restrained.
- Never attach two child safety seats to the same anchor. In a crash, one anchorage may not be strong enough to hold two child safety seat attachments and may break, causing serious injury or death.
- The standardized spacing for LATCH lower anchors is 11 inches (28 centimeters) center-to-center. Do not use LATCH lower anchors for the center seating position unless the child seat manufacturer's instructions permit and specify using anchors spaced at least as far apart as those in this vehicle.
- The lower anchors at the center of the second-row bench seat are spaced 520 mm (20.5 inches) apart. The standardized spacing for LATCH lower anchors is 280 mm (11 inches) center-to-center. A child seat with rigid LATCH attachments cannot be installed at the center seating position. LATCH compatible child seats (with attachments on belt webbing) can only be used at this seating position provided that the child seat manufacturer's instructions permit use with the anchor spacing stated. Do not attach a child seat to any lower anchor in an adjacent child seat that is attached to that anchor.

Manufacturer's Option To Provide Dedicated Lower Anchorages, and To Recommend or Not Recommend Sharing Lower Anchorages

The Alliance explained that manufacturers need to balance the necessity for CRS anchorages with other customer requirements like seat adjustments, the location of seat belts, etc., and that often vehicle packaging precludes providing a dedicated set of center lower anchorages. The Alliance added that many vehicles (*e.g.,* small cars and vehicles where the rear seat is between the wheel wells) are not wide enough to accommodate three distinct CRAS-equipped positions. The Alliance stated that even where the rear seat is wide enough, the vehicle may have insufficient structure to carry the simultaneous loading of three sets of anchorages.

The Alliance further commented that in certain vehicles, components such as a seatback adjuster would not provide the space required for a dedicated third set of lower anchorages. The Alliance added that vehicles using a separate fore/aft seat movement in a split rear seat may not be able to accommodate two pairs of lower anchorages on an individual section of the seat.

The Alliance explained that vehicle manufacturers have, for various reasons, equipped certain vehicles with the potential to attach a child seat in the rear center seating position while not providing three distinct sets of child restraint lower anchorages in the rear. As an example, the Alliance pointed to a vehicle configuration using a 60–40 split rear seat with greater than 710 mm between the centerlines of the outboard lower anchorages. Instead of a third set of lower anchorages, the vehicle is equipped with a ''fifth'' lower anchorage provided to create a set of center anchorages by ''borrowing'' from the inboard anchorage of the adjacent seating position.[132] The Alliance stated

[131] Klinich, K.D., Manary, M.A., Orton, N.R. ''Feasibility of Center LATCH.'' NHTSA–2014–0123–0007.

[132] As illustrated in figure 20 of the Alliance comments in Docket No. NHTSA–2014–0123–0027.

Continued

that this arrangement allows for the potential to attach either a center child restraint or an outboard child restraint (on the 60 percent seat side). The Alliance added that other solutions to provide center anchorages in small vehicles have led to customer confusion, such as where anchorage locations overlap, causing customer confusion as to which anchorages created a ''pair'' to install a child restraint equipped with flexible attachments.

The Alliance explained that the space required by a child restraint system and the location and accessibility of the lower anchorages are regulated by using a Child Restraint Fixture (CRF),[133] and that the dimensional characteristics of a CRF were developed to represent a typical child restraint system. The Alliance further explained that in a vehicle with over 710 mm between the centerline of the two outboard lower anchorages, three CRFs (that represent a child restraint system) [134] are not feasible in the same row at the same time, and thus requiring manufacturers to design a vehicle with three sets of lower anchorages is not practicable because installing three child restraints simultaneously in such vehicles cannot be achieved in the field. The Alliance therefore stated that it recommends that NHTSA not require a dedicated set of center lower anchorage in addition to the two outboard lower anchorages.

The Alliance next described a mid-sized SUV with a distance between the centers of outboard seating positions of 800 mm, and the distance between the inboard lower anchorages of 520 mm.[135] The Alliance explained that customer expectations for split back, reclining, fold flat seatbacks, center fold down armrest, and an expectation for a bias in roominess and comfort at the second row outboard positions would preclude the addition of dedicated lower anchorages in the center position. The Alliance added that a caregiver still has the option to use the center seat belt to secure a child restraint in that position.

The Alliance stated that there are circumstances where it is permissible to install a CRS that has flexible lower anchorage attachments in the rear center location using a simulated restraint anchorage system. However, it explained that in order to do so, several factors need to be considered and controlled. Specifically, the Alliance listed the following considerations:

- The center position must be a DSP (or else a CRS installed using the outboard anchorages might be very unstable). The Alliance explained that in vehicles without a center DSP, simulated rear center child restraint locations are typically not permitted by the vehicle manufacturer.
- The spacing between the anchorages must be within a range acceptable to both the vehicle and CRS manufacturers and that for rigid anchorage CRSs with fixed spacing, this will be a significant limitation.
- The vehicle seats must be positioned such that the lower anchorage bars on the outboard seats are collinear (*i.e.,* one seat cannot be positioned either forward or rearward of the other). Alliance explained that this can occur if the two seating positions can be moved fore/aft independently.[136]
- The CRS manufacturer must not recommend against use of non-standard spacing for the particular CRS model.
- There must be no more than one CRS attached to any lower anchorage, and,
- There must be no contact or obstruction between the CRS lower anchorage straps and vehicle safety belts being used in the outboard positions (such contact could damage the straps and/or the belts and could adversely affect initial belt routing and/or safety performance in a crash).[137]

The Alliance stated it would be difficult to effectively communicate these limitations to the majority of consumers. The Alliance added that some manufacturers allow the use of ''simulated'' center anchorage positions in specific vehicles that meet the above conditions but that the majority of vehicle/seat configurations may not safely accommodate such fitment. As a result, the Alliance explained that vehicle manufacturers provide vehicle-specific guidance to consumers about when it is appropriate to use the simulated center anchorage position as well as instructions for using the simulated center anchorage position. The Alliance further stated that the LATCH Manual (published by Safe Ride News) also documents the vehicles that provide this option; however, since such fitment cannot be universally applied to all vehicles, seating configurations, and CRSs, the Alliance does not recommend that the agency issue a ''blanket'' recommendation in this area.

The Alliance also commented that there is no regulatory test device to assess the strength of simulated CRAS. The Alliance explained that neither the SFAD 1 nor the SFAD 2 can be used to test a set of lower anchorages spaced wider than 11 inches apart. The Alliance recommended that a standardized test fixture and test procedure should be developed for both the CRS manufacturers (to assess integrity and performance in frontal and side impacts) and for the vehicle manufacturers (to assess anchorage strength) if the agency wishes to encourage wider acceptance of simulated center anchorage systems in vehicles.

The Alliance commented that another concern with the simulated rear center CRAS is that consumers may attach two child restraint systems to the inboard anchorage of an outboard seating position. The Alliance explained that in such cases, the combined loading from two CRSs might overload the single lower anchorage, causing it to fail in a crash. The Alliance stated that although manufacturers can provide warning statements in their owner's manuals for such a scenario,[138] this does not prevent caregivers from making this error. The Alliance further stated that this misuse scenario is why manufacturers do not support such simulated rear center anchorage systems.

Dr. Baer added that studies of both adults and children show that the center is the safest spot in the back seat,[139] and as such, the focus should be put on requiring vehicle manufacturers to design their center seats in ways that accommodate a car seat. Dr. Baer further stated that the proposed requirement for the installation of center lower anchorages in vehicles with 710 mm or

Link: *www.regulations.gov/comment/NHTSA-2014-0123-0027.*

[133] As defined and shown in FMVSS No. 225, figure 2.

[134] As illustrated in figure 21 of the Alliance comments in Docket No. NHTSA–2014–0123–0027. Link: *www.regulations.gov/comment/NHTSA-2014-0123-0027.*

[135] As illustrated in figure 22 of the Alliance comments in Docket No. NHTSA–2014–0123–0027. Link:*www.regulations.gov/comment/NHTSA-2014-0123-0027.*

[136] As illustrated on page 28 of the Alliance comments in Docket No. NHTSA–2014–0123–0027. Link: *www.regulations.gov/comment/NHTSA-2014-0123-0027.*

[137] As illustrated in figure 23 of the Alliance comments in Docket No. NHTSA–2014–0123–0027. In this example the Alliance showed that while there is good access to the seat belt buckle for the adjacent seating position, interference with the CRS lower anchorage strap could adversely affect the positioning of the lap belt on an adjacent occupant (in this case it would cause the lap belt to be positioned high on a small occupant, increasing the potential for submarining). Link: *www.regulations.gov/comment/NHTSA-2014-0123–0027.*

[138] Alliance provided an example of an owner's manual warning in its comments (page 30) in Docket No. NHTSA–2014–0123–0027. Link: *www.regulations.gov/comment/NHTSA-2014-0123-0027.*

[139] Kallan, M.J., Durbin, D.R., and Arbogast, K.B. ''Seating Patterns and Corresponding Risk of Injury Among 0- to 3-Year-Old Children in Child Safety Seats'' Pediatrics 2008 and Mayrose, J.S. and Priya, A. ''The safest seat: effect of seating position on occupant mortality'' J Safety Res. 2008.

more space between the centerlines of the outboard lower anchorages is an important step to increasing the number of vehicles on the road that can more easily accommodate CRSs in a wider variety of configurations and installation methods.

Center Seat Use of Simulated Lower Anchorages Only When CRS and Vehicle Allow It

Graco encouraged the CRS and vehicle manufacturers to include statements on whether they endorse the use of simulated CRAS in rear center seating positions in instruction manuals. However, Graco did not support a requirement on the use of simulated center seat anchorages, as some vehicles may have split center seating that would cause the possibility of misuse by the consumer. Graco further explained that CRS connector designs may be limited in their tolerance for attachment to the vehicle anchorages. As such, Graco explained that it recommends an instruction manual recommendation for simulated center seat anchorage use only when both the vehicle and CRS manufacturers would allow its use.

Dr. Baer commented that while many parents are creating their own simulated CRASs in the center of their vehicles (when the vehicle and CRS manufacturers prohibit it), she is concerned that the simulated CRAS as presented in the NPRM may increase injury risk for the following reasons:

1. Dr. Baer stated that when the simulated position's lower anchorages are wider than 11 inches, the lower anchorage hardware typically crosses over the seat belt buckle for both side seats—meaning that an adult trying to ride in back will not be able to wear a seat belt, which is clearly a dangerous situation not only for the adult, but everyone else in the vehicle as well.

2. Dr. Baer stated that when the simulated position has one lower anchorage that is shared with one of the side seats, several issues arise, including that the shared lower anchorage typically blocks the seat belt buckle for the side seat, or caregivers may try and attach two car seats to one lower anchorage.

3. Dr. Baer commented that simulated positions may have interference with the usage of the side seat belt buckles. She further commented that the interference is less in vehicles that offer side seat belt buckles that are on a flexible webbing stalk, instead of those that are on rigid stalks and/or are flush mounted with the vehicle seat cushion. However, Dr. Baer stated that all vehicles should allow simulated lower anchorages, as there are cases where a caregiver does not have adults riding in back, and/or the lower anchorage strap does not interfere with adjacent seat belt hardware.

4. Dr. Baer stated not all CRs in the United States allow for an installation with lower anchorages spaced wider than 11 inches, which might cause more confusion over where and when a lower anchorage installation is permitted.

Agency Response

After careful review of comments received, NHTSA has decided not to include any new requirements on the center seating position if a center DSP is available. The agency does not believe that a 710 mm [140] rear width criterion for determining whether a dedicated lower anchorage should be required is sufficient, as other design factors brought up by commenters come into play to ensure correct use. Specifically, the rear seat environment is complex and such a requirement could limit vehicle manufacturer design options to provide features in high demand by consumers, such as foldable seatbacks. The agency is concerned that new requirements might have unintended consequences, such as vehicle manufacturers opting to make vehicles without a center DSP to accommodate high demand features such as foldable seats instead of a center DSP that can be used to install a CRS with seat belts. Additionally, the UMTRI study that determined the 710 mm width in rear seats did not account for the complexities of vehicle designs with hardware for foldable seats.[141] Further, at this moment, the agency does not have an estimate of how much space is necessary to include such features and how difficult it is to accommodate both features (dedicated center lower anchorages and seat folding hardware). The 710 mm rear width criterion is too simplistic as it cannot account for a set of more complex designs and NHTSA would need further studies to develop requirements that would be more encompassing of vehicle designs that won't risk the elimination of the center designated seating position by the manufacturer.

NHTSA has also decided not to require vehicle manufacturers to recommend a simulated lower anchorage center seating position if a center DSP is available. NHTSA made this determination after careful review of concerns raised by manufacturers, who pointed out several issues with simulated lower anchorages in the center seating position that could increase misuse of the anchorages, including: (1) where a vehicle rear seat is split (50/50 or 60/40) and can be moved for-aft, the lower anchorages, being in different sections of the rear seat, may not be collinear; (2) the consumer would have to be aware that only one CRS can be used on a simulated anchorage; (3) both CRS and vehicle manufacturers must allow the use of non-standard lower anchorages spacing; (4) the spacing between the simulated center lower anchorages must be within a specified range that is acceptable to both vehicle and CRS manufacturers; and (5) installing a CRS in a simulated lower anchorage center position should not interfere with the safety belts being used in the outboard positions such that they could be damaged or produce a bad belt fit for the outboard occupant.

NHTSA agrees with SRN, Ford, and IIHS's suggestion that the option to provide a dedicated or simulated center lower anchorage seating position should be left to the vehicle manufacturer. NHTSA believes that vehicle manufacturers should determine whether they will provide a lower anchorage equipped center seating position (if a center DSP is available) by including a dedicated set of lower anchorages, or recommending a simulated one, as they can take into consideration all the other design restrictions and requirements they have. Manufacturers must also make the choice on whether there may be no lower anchorage in the center seating position.

In summary, the agency will not adopt additional requirements in vehicles to provide means of installing a CRS in the center seat using simulated lower anchorages at this time. The different designs in vehicles make it difficult to standardize certain aspects of the lower anchorages and the agency has not fully evaluated the impact of some of the requirements on all the vehicle models. For this reason, NHTSA believes that the recommendation of using the CRAS in the center seat (if a dedicated one is not provided) is best left for the vehicle manufacturer to decide and establish the conditions on how they should be used (*i.e.,* for/aft seating position on a split bench, seat belt interference, etc.). NHTSA encourages vehicle and CRS manufacturers to provide in their owner's manuals instructions to the consumer on how and if simulated lower anchorages can be used for a center seating position. Consumers

[140] The 710 mm rear seat width limit was determined by UMTRI 's NHTSA-sponsored study.

[141] Klinich, K.D., Manary, M.A., Orton, N.R. ''Feasibility of Center LATCH.'' NHTSA–2014–0123–0007.

should be directed to see both vehicle and CRS instruction manuals to decide whether they can use and how to use a non-standard lower anchorage in the center seat.

Recommendation To Not Install CRSs in the Rear Center Seat if There Are No Dedicated Lower Anchorages

Dr. Baer commented that a few MY2015 vehicles have two dedicated lower anchorages in the center position (for a total of 6 lower anchorages in the rear seat) that do not crisscross with any of the other lower anchorages. However, for these vehicles, Dr. Baer explained that the spacing between some of the lower anchorages is so close together (often less than 2 inches apart) that it is impossible to install 2 CRSs side-by-side in the center and side position, as CRSs are typically 6–10 inches wider than the 11 inches between their lower anchorage connection points.

Dr. Baer proposed that if a center seating position does not have lower anchorages, it must be assumed that the position was likely too narrow to accommodate it, and the vehicle manufacturer must clearly state in its owner's manual that this position is too narrow to accommodate a car seat or booster. Dr. Baer also stated that the issues with the lack of usability of the center seat extend beyond the lower anchorages. Specifically, she asked why it is acceptable for vehicle manufacturers to sell a vehicle (especially one targeted to families) where it is impossible to secure any CRS to the center seat without taking up the adjacent seating position by virtue of the CRS blocking an adjacent position's seat belt buckle. Dr. Baer stated that several vehicles cannot accommodate a car seat in the center without sacrificing the rear driver's side seat, turning the vehicle into a 2-seater back seat instead of a 3-seater. Dr. Baer stated this is something that dealerships do not mention to families, nor do all of the manuals clearly explain it.

Agency Decision

NHTSA disagrees with Dr. Baer's suggestion that if a center seating position does not have lower anchorages it must be assumed that the position was likely too narrow to accommodate it. NHTSA also disagrees with Dr. Baer's suggestion that in this scenario the vehicle manufacture must clearly state in its owner's manual that the position is likely too narrow to accommodate a car seat or booster seat. While NHTSA recognizes concerns that in some cases the center seat may be too narrow to accommodate some wider CRS designs, or a passenger in an outboard seating position when a CRS is installed in the center seating position, we disagree that vehicle manufacturers should prevent CRSs from being installed in the center designated position where no lower anchorages exist. Requiring manufacturers to prohibit the use of CRSs in the center seat when the seat is too narrow will eliminate the option for parents or caregivers to install the seats (with seat belt or with non-standard lower anchorages if allowed) in the center seat based on their need to accommodate all passengers.

Finally, in response to Dr. Baer's comment raising questions on the appropriateness of vehicle manufacturer sales practices to families, NHTSA will not address this comment as it does not relate to the proposals in the NPRM and is outside the scope of this rulemaking.

Requiring Dedicated Center Lower Anchorages With Standard Spacing To Accommodate Rigid Lower Anchorage Attachments

ARCCA recommended providing lower anchorages for the center rear occupant position, stating research has shown that a CRS properly secured in the center rear occupant position provides the most effective occupant crash protection. ARCCA added that research also indicates that CRSs secured by CRASs provide superior occupant crash protection compared with CRSs secured by a seat belt, especially in side impacts, and that rigid-lower-anchorage-attachments-secured CRSs provide the greatest amount of side impact crash protection. ARCCA stated that while the center rear seat may not be plausible when there is more than one child,[142] many couples only have one child, and those that have more children typically only have one initially, so many children can be secured in the center rear occupant position.

ARCCA stated that for optimal crash protection a child should be properly secured in the center rear occupant position in a CRS with rigid lower anchorage attachments. In addition, ARCCA commented that CRSs incorporating rigid lower anchorage attachments have recently become available in the U.S and that parents choosing to use these CRSs for the increased crash protection should not be forced to compromise that crash protection by having to place the CRS in an outboard location, when the center position is available but does not have lower anchorages. ARCCA also recommended that labels and color coding be used to prevent confusion over which anchorages correspond to each occupant position. ARCCA explained that manufacturers integrate seat belt anchorages in the same general area as the lower anchorages, and that the seat belt anchorages are able to withstand much higher loads than what a lower anchorage sustains when restraining a high weight CRS. Therefore, ARCCA stated that increasing the strength of the lower anchorages is also readily technically feasible.

Agency Decision

As previously stated, this final rule will not require a CRAS in the rear center seating position, but will permit manufacturers to voluntarily include a CRAS in rear center seating positions, or recommend a method of attaching CRSs using CRASs (sharing outboard anchors) in the rear center seat. This approach balances safety, ease of use, and design flexibility. NHTSA acknowledges ARCCA's recommendation that a dedicated center position should be available to accommodate CRSs with rigid lower anchorage connectors; however, as explained previously, a dedicated set of anchorages in the center seat is not always feasible due to space restrictions. Further, CRSs with rigid lower anchor connectors make up a very small number of CRSs in the field. As such, requiring lower anchorages in the center seating position to install CRSs with rigid lower anchor connectors would not add significant benefit as the CRS can also be safely installed using the seat belt. ARCCA expressed that many parents have only one child, or one child initially, and stated that they should be able to use the center seat for installing the CRS. Because center seating positions provide seat belts, CRSs can be installed in the center seat with a seat belt, or, if available, lower anchorages; therefore, NHTSA, does not see this issue as concerning. As stated earlier, parents or caregivers will have the option of installing CRSs with rigid lower anchor connectors with the seat belt in the center seating position or in an outboard position where a dedicated lower anchorage set should be available.

Additionally, ARCCA recommended labels and color coding be used to prevent confusion over which anchorages correspond to each occupant position. Since NHTSA is not adopting any new requirement for additional lower anchorages (dedicated or shared), NHTSA is not adopting any labels or color coding to identify the lower anchorages per seating position. As NHTSA did not propose any labels and color coding to identify the lower

[142] The agency observes that many CRSs are difficult to install adjacent to each other because they are wide and occupy part of the adjacent seat.

anchorages per seating position, adopting these requirements for vehicles that voluntarily provide additional anchorages would fall outside the scope of this rulemaking and will thus not be addressed by this final rule.

Finally, increasing the lower anchorage strength requirements, as suggested by ARCCA, was not addressed in the proposed rule and will not be addressed as it is out of scope of this rulemaking.

Spacing of Non-Standard Lower Anchorages

Dorel and JPMA stated that virtually all CRS designs in the U.S. use flexible lower anchor connectors (as opposed to rigid), which are capable of installation using a child restraint-equipped flexible anchorage system with varying vehicle center position spacing widths. Dorel observed that test data indicate that CRASs attached to lower anchorages of widths greater than the standard 280 mm have crashworthiness that performs satisfactorily.

JPMA requested that NHTSA evaluate and provide guidance on the potential of standardizing the spacing of the non-standard lower anchorages. JPMA suggested having an allowance in the standard seat test bench assembly to accommodate some distance of spacing. JPMA explained this would afford CRS manufacturers the opportunity to choose whether to allow the use of CRASs with their seats and that NHTSA could conduct compliance tests if this is the case. JPMA requested NHTSA's guidance in determining the non-standard spacing to allow for the potential redesign of the CRAS anchorages to accommodate the angular pull of the lower anchorages and lower anchor connectors during the crash testing.

Britax stated it has not evaluated or tested the variety of simulated child seat anchorage spacing that might be presented by diverse vehicle rear seat designs. Britax suggested that the analysis presented in the NPRM [143] may be useful in providing guidance so that the use of simulated child seat anchorages requires at least a minimum spacing between the simulated child seat anchorages.

Agency Response

In response to JPMA's request that NHTSA evaluate and provide guidance on potentially standardizing the spacing of non-standard anchorages (with an allowance in the standard seat test bench assembly to accommodate greater spacing of lower anchorages), NHTSA understands this comment to suggest that CRS manufacturers would want a certification test in FMVSS No. 213 [144] with different lower anchorage spacing in order to recommend/allow it in their manuals.

NHTSA does not plan to add this additional certification test to FMVSS No. 213, as the agency's dynamic front and side sled testing showed no significant changes to anchorage loads or CRS performance that would justify these additional test burdens. Were NHTSA to require vehicle manufacturers to provide a non-standard lower anchorage center seating position (shared or adding a 5th anchorage, etc.), it is highly likely that CRS manufacturers will prohibit it.[145] As such, NHTSA would have imposed a burden on vehicle manufacturers for features that will not be used.

In response to JPMA's request for guidance in determining the non-standard spacing to allow for the potential redesign of the lower anchorages to accommodate their angular pull during the crash testing, the agency points out that NHTSA-funded sled tests using non-standard lower anchorage spacing showed that increasing the lower anchorage spacing did not affect the injury measures of the dummies used in the frontal and side impact sled tests.[146] The updated standard seat assembly (Docket No. NHTSA–2023–0040) for the frontal and side impact tests for CRSs per FMVSS No. 213b and FMVSS No. 213a, respectively, permits changing the width of the anchorages with ease. CRS manufacturers may voluntarily conduct additional testing with greater anchorage spacing than the standard 280 mm to determine whether to permit CRS installation in vehicle seats using CRASs with anchorage spacing greater than 280 mm.

Finally, regarding Britax's suggestion to use the NPRM data analysis to provide guidance to establish at least a minimum spacing between the simulated child seat anchorages, the agency is not currently issuing any guidance on non-standard spacing, but CRS and vehicle manufacturers may use the NPRM's data analysis to explore their own recommendations.

b. Third Row

Currently, FMVSS No. 225 requires that at least one of the two required CRASs be installed at a second-row seating position in each vehicle that has three or more rows. A number of comments to the 2007 LATCH public meeting expressed dissatisfaction with the number of CRASs present in the third row of vehicles. Specifically, some commenters stated that consumers sometimes purchase vehicles with three or more rows to accommodate large families but are unable to install all of the child restraints with a CRAS because the third row does not have available systems.

The agency examined data and comments from the February 25, 2011,[147] request for comments on the proposed NCAP Vehicle-CRS Fit program. The information reviewed indicates there is only a small percentage (2.4 to 4.5 percent) of children in CRSs with internal harness (CRSs that would use the lower anchorages) using the third row, and that the reduced space in the third row makes it difficult to fit most rear-facing CRSs.

The NPRM stated that due to the lower anchorages (plus tether anchorage) weight limit of 29.5 kg (65 lb) combined weight (CRS + child) and car seat use recommendations developed by NHTSA and the AAP that children should stay in a rear-facing CRS for as long as possible, most CRSs installed with lower anchorages will be rear-facing ones; therefore, the use of the lower anchorages in the third-row might only be for a relatively short period for forward-facing restraints.

NHTSA's 2015 NPRM requested comment on the following:

- Whether FMVSS No. 225 should require CRASs or tether anchorages in all rear seating positions.
- Would requiring CRASs or tether anchorages in all rear seating positions meet the need for motor vehicle safety?
- Would requiring CRASs or tether anchorages in all rear seating positions protect the public against unreasonable risk of death or injury in an accident?
- Whether FMVSS No. 225 should require CRASs in the third row if it is not altogether feasible to use rear-facing CRSs in the third-row due to reduced space in that row.

[143] Amenson, T., Sullivan, L.K., ''Dynamic Evaluation of LATCH Lower Anchor Spacing Requirements and Effect of Tether Anchor Location on Tether and Lower Anchor Loads.''

[144] FMVSS No. 213 will be replaced by FMVSS No. 213b on December 5, 2026.

[145] For example, most CRS manufacturers currently prohibit the use of inflatable seat belts and the use of their products in a non-front facing vehicle seat. Manufacturers stated that their products are not certified for those conditions, and, therefore, prohibit them (even though research shows they perform well with inflatable seat belts and in any direction crash).

[146] Amenson, T., Sullivan, L.K., ''Dynamic Evaluation of LATCH Lower Anchor Spacing Requirements and Effect of Tether Anchor Location on Tether and Lower Anchor Loads,'' NHTSA, 2013. *www.regulations.gov/document/NHTSA-2014-0123-0004.*

[147] 76 FR 10637. *See www.govinfo.gov/content/pkg/FR-2011-02-25/pdf/2011-4212.pdf.*

- The likelihood of consumers placing rear-facing CRSs in the third row, even if CRSs could fit in that row. Even if rear-facing child restraints could not or would not be installed using CRAS in the third row of a vehicle, are CRAS needed in the third row for forward-facing CRSs?
- Would an amendment requiring CRASs or tether anchorages at some or all third-row seating positions meet the requirements and considerations of section 30111(a) and (b) of the Vehicle Safety Act?
- The feasibility of installing CRASs and tether anchorages in some or all rear seating positions in vehicles with three or more rows.

Comments

In response to these questions, three commenters (SRN, IIHS, and UMTRI) supported requirements for additional lower anchorages and/or tether anchorages in the third row of vehicles (if available). The Alliance stated that additional anchorages should be optional, and Britax stated that additional anchorages systems in the third row would not likely result in increased harnessed seat installations.

Support for Tether Anchorages in All Rear Seating Positions

SRN, IIHS, and UMTRI strongly recommended requiring tether anchorages in every rear seating position. IIHS further stated that parents have the option of installing a child restraint with the vehicle seat belt in lieu of lower anchorages, but that there is no substitute for a tether anchorage when installing a forward-facing child restraint. IIHS explained that providing parents with a tether anchorage in all rear seating positions will not only provide additional flexibility in where child restraints can be installed, but also potentially increase awareness and use of tether anchorages, as parents would know they could expect to see a tether anchorage in every seat.

Support for Additional CRAS-Equipped Seating Positions in the Third Row

SRN stated that consistently providing at least one CRAS for the third row would be helpful. SRN explained that there are few CRASs provided for third rows in vehicles and that in MY 2014 vehicles there were 18 models with at least one CRAS in the third row (many of these being full size vans that are not typical family vehicles). SRN commented that having additional CRAS equipped seating positions in the third row would ease installation in the cramped environment of a third row. SRN explained that CRS installation in third rows is even more difficult than usual as seat belts are sometimes anchored to the ceiling and back wall, and these types of vehicles often have more difficult geometry for use with CRS installation and/or are the dual-buckle variety that confuses many caregivers.

SRN, IIHS, and UMTRI encouraged requiring additional CRASs in the third row of vehicles. IIHS stated that the NPRM suggested that there may be limited benefit for CRAS hardware in the third row because of the relatively short time that children are in forward-facing child restraints, but commented that CRASs can beneficial longer than NHTSA anticipates. IIHS explained that according to the most recent National Survey on the Use of Booster Seats (NSUBS),[148] nearly three-quarters of children aged 1 to 3 years, almost a third of those aged 4 to 5 years, and an increasing number of those aged 6 to 7 years are seated in forward-facing child restraints. IIHS added that booster seats are increasingly available with lower anchorage connectors, increasing the likelihood that lower anchorages will be used after children transition from the forward-facing child restraints to boosters.

UMTRI commented that vehicles with more than one row of rear seating should be required to have at least two sets of lower anchorages and tether anchorages at every seating position in each row. UMTRI explained that families that purchase vehicles with multiple rows of seating usually plan to have children sit in all the rear seating positions at some point during the life of the vehicle. Additionally, UMTRI stated that even if families are not going to use all of the lower anchorages simultaneously, it would be beneficial for families to have options as their needs evolve. UMTRI explained that the youngest children might first sit in the second row to be closer to adults, and that families with a mix of preschool and school-aged children might put children in harnessed restraints in the third row to allow easier ingress and egress during carpooling for older children using booster seats in the second row.

Support for Optional Anchorages in Third Row

The Alliance commented that the installation of child restraint lower anchorages in the third row should remain optional based on the following assertions:

- The safety belt provides an acceptable alternative for restraining a harness CRS in the third row.
- Usage of rear and forward-facing harness CRSs in the third row is low; data gathered from 87,655 Safe Kids Worldwide checklist forms from January 1, 2013, through December 31, 2013, indicate that only 1.7 percent of all children sit in the third row in either a rear-facing or forward-facing harness CRS that could use lower anchorages.[149]
- Forward-facing harness CRS cannot use lower anchorages above a combined weight of 65 lbs., which will limit their usage of lower anchorages, further decreasing the potential usage of lower anchorages in the 3rd row.

The Alliance added that as smaller vehicles continue to be introduced for fuel economy purposes, it becomes difficult, if not impracticable, to install a rear-facing CRS in the third row in certain of these smaller vehicles due to space limitations. The Alliance added that even if a rear-facing CRS can be fitted in the third row of these smaller vehicles, it may not be possible for a passenger to be seated in the second-row seat when a rear-facing CRS is installed in the third row.[150] The Alliance stated that in these cases customers will naturally choose to install the CRS in the second row rather than the third row, rendering the CRAS in the third-row unnecessary.

Britax commented that, according to its installation polling, consumers frequently cannot easily access third-row seats for harnessed child restraint installation. Britax explained that rear-facing installation involving children under the age of two is even more unlikely, as third-row seating tends to be relegated to older children who can perhaps buckle themselves into booster seats or in a belted seat position. Britax added that the vehicle interior space between many third-row seats and rear vehicle doors may prevent the installation of either rear-facing harnessed seats or tether usage generally. Finally, Britax stated that mandating anchorage systems in third-row seating would not likely result in increased harnessed seat installations.

Agency Response

After careful consideration the agency has decided not to require additional lower anchorages or tether anchorages in vehicles with more than three rear designated seating positions.

[148] NSUBS publications: *https://crashstats.nhtsa.dot.gov/#!/PublicationList/20.*

[149] Alliance comments in Docket No. NHTSA–2014–0123–0027.

[150] As illustrated on figure 24 of Alliance Comments. *See* Docket No. NHTSA–2014–0123–0027. Link: *www.regulations.gov/comment/NHTSA-2014-0123-0027.*

CRSs equipped with harnesses to restrain the child are not widely used in the third rows of vehicles,[151] which supports comments received that for the most part forward-facing CRSs and rear-facing CRSs do not fit in third rows (without having to make the front seat unusable). As these areas are seldomly used and seat belts offer a safe alternative to install forward-facing CRSs to higher combined weights, requiring additional lower anchorages in the third row offers no significant benefit to justify the cost and weight added to the vehicle.

NHTSA acknowledges comments made by UMTRI, IIHS, and SRN indicating that increased availability in lower anchorages and tether anchorages in the third row would offer added flexibility and options to caregivers when installing CRSs. However, we agree with comments received that the limited space in many third rows would make it difficult for a child to have enough space to be seated in a rear-facing or forward-facing CRS (without making the seat in front unusable by pushing it forward or folding the seatback), thus limiting the use of third rows for transporting children in rear-facing and forward-facing CRSs. The agency encourages vehicle manufacturers to continue voluntarily providing additional lower and tether anchorages where feasible, especially in vehicles designed for families (*e.g.,* mini vans, SUVs) as those consumers would likely be seeking the most flexibilities to transport children in CRSs.

c. Terminology

The agency requested comment on whether the written information [152] provided pursuant to Standards No. 225 and No. 213 using standardized terminology referring to the parts of the CRAS and the components of the child restraint that connect the CRS to the vehicle would help improve the ease of use of CRAS.

NHTSA also requested comment on whether requiring the following terms in child restraint and vehicle user's manuals would help make instructions clearer and more uniform: ''lower anchor(s)'' and ''tether anchor'' for components of the vehicle CRAS, and ''lower anchor attachments'' and ''tether'' for components of the CRS that are used to connect the CRS to the vehicle. A ''lower anchor attachment'' is comprised of a ''lower anchor connector'' and a ''lower anchor strap'' (for flexible lower anchor attachments), and a ''tether'' is comprised of a ''tether hook'' and a ''tether strap.''

Comments

Graco recommended that NHTSA update FMVSS No. 213 with the same terminology for lower anchorages and tether anchorage so that there is no confusion with how the labels will read verses the requirements in the NPRM. For example, Graco pointed out that currently section S5.5(j) of FMVSS No. 213 says ''Secure the top anchorage strap provided with this child restraint.'' However, according to Graco, per the NPRM's proposal it should say ''Secure the tether provided with this child restraint.'' Graco also commented that section S5.6.1.12(a) of FMVSS No. 213 says ''Do not use the lower anchorages of the CRAS (LATCH system) to attach this child restraint when restraining a child weighing more than . . .'' Graco asked for clarification on whether the term ''(LATCH system)'' should be included in the statement.

Similarly, Dorel stated that the use of the acronym LATCH, as required by FMVSS No. 213, can be confusing to consumers. Dorel explained that the English language's use of the word ''LATCH'' has several meanings, one of which describes a device that holds a door, gate or window, and another referring to a mechanical device that engages in order to ''fasten.'' Dorel added that the word LATCH implies a single device, and not multiples of devices or functions which combined make up a system. Dorel explained that the plain language use of terms in child restraint and vehicle user's manuals should help make the instructions clearer and more uniform. Dorel agreed that use of plain words such as the proposed ''lower anchor(s)'' and ''tether anchor,'' or ''lower anchor attachments'' and ''tether'' for components, are in fact more descriptive of the word's intended purpose than a single acronym that could be confusing.

Dorel further explained that for bilingual members of the U.S. population, especially those for whom English is a second language or other comprehension factors are involved, ''lower'' and ''top'' can be confusing language modifiers. By way of example, Dorel pointed to mini-vans and SUVs that have tether anchorages at the base of the vehicle seat or on the floor behind the vehicle seat. Dorel explained that when the ''lower anchorages'' are higher than the ''top anchorage,'' comprehension can become quite challenging. Dorel stated that requiring installation diagrams labeled with standardized terminology could help with comprehension. Britax also indicated support for efforts to standardize common terminology related to anchorage systems and requested additional time to incorporate such changes into its CRS printed materials. SRN agreed that uniform terminology would help to make CRAS instructions clearer and less confusing. SRN stated that given the proposed new requirements for instructions explaining the new CRAS markings, it seems reasonable to make sure that those instructions have uniformity of terms. SRN added that it is comfortable with the terms proposed.

Dorel stated that standardized terminology, combined with associated symbols, would improve consumers' ability to comprehend the intended function of a system made up of separate components. Dorel further indicated that this would increase the likelihood of the correct use of child restraints. UMTRI agreed that the use of the term LATCH may mask the importance of the tether component of the system; however, UMTRI stated that avoiding the term LATCH doesn't necessarily reduce confusion, as it has been in widespread use for over 16 years. Similarly, IIHS supported the use of consistent terminology and the explicit use of the proposed terminology in owner's manuals but encouraged NHTSA to continue to allow and encourage the term LATCH to refer collectively to the dedicated CRAS and associated child restraint hardware. IIHS explained that changing to new terminology at this point in lieu of the term LATCH would confuse parents with no apparent off-setting benefit.

IIHS further stated that it is prudent to have the ability to refer to all the anchorage hardware in one efficient phrase, while clearly specifying lower anchorages and tether anchorages when necessary. IIHS also stated that the phrase ''child restraint anchorage system'' is ambiguous and cumbersome and does not convey the important message that lower anchorages and tether anchorages are hardware distinct from safety belts, as belts could also be considered a CRAS. Finally, IIHS stated that the absence of the term LATCH in

[151] NHTSA conducted the National Child Restraint Use Special Study (NCRUSS) in 2011, observing the use of car seats and booster seats for child passengers (birth to 8 years old) in 4,167 vehicles. The NCRUSS is a nationally representative survey. This study found that less than 3 percent of children in the study were seated in the third row of the vehicle. Greenwell, N.K. (2015, May). Results of the national child restraint use special study. (Report No. DOT HS 812 142). Washington, DC: National Highway Traffic Safety Administration.

[152] Standard No. 225 (S12) requires vehicle manufacturers to provide written instruction for using child restraint anchorage systems and tether anchorages. Standard No. 213 (S5.6.1) specifies that child restraint systems provide printed instructions that include a step-by-step procedure for installing and securing the child restraint system in a vehicle.

the NPRM and NHTSA's website might suggest the term LATCH is discouraged.

UMTRI suggested that the term LATCH continue to be used, while employing additional efforts to emphasize the tether component. UMTRI stated that some of the confusion over the term LATCH stems from the requirement by NHTSA to refer to LATCH anchorages and connectors as the ''child restraint anchorage system.'' UMTRI further stated that if NHTSA harmonized terminology and permitted the use of the term LATCH in required labeling it would do more to reduce confusion than discontinuing use of the term LATCH. UMTRI also suggested requiring vehicle owner's manuals to include language to convey the idea that the tether component of the LATCH system must be used when installing forward-facing car seats using the seatbelt. UMTRI explained that many vehicle manuals do not mention or emphasize this point.

UMTRI also stated that it would be helpful if vehicle manuals included directions on how to use and route single strap or V-style tethers in relation to the vehicle interior components, such as head restraints. UMTRI stated it preferred the term ''LATCH belt'' to ''lower anchor strap,'' as the word belt emphasizes that either the seatbelt or the LATCH belts are the primary means of attaching the CRS. Finally, IIHS stated that standardized terminology should include a term for rigid lower anchorage connectors, found on several booster seats in the U.S. market.

Agency Response

The agency acknowledges several comments indicating support for a standardized terminology and/or agreement with the terms proposed in the NPRM to have more consistent education messages and user manuals to improve the ease-of-use of CRASs. The agency also acknowledges commenters who stated that removing the term LATCH could cause more confusion to consumers, as parents will have to be re-educated with new terminology.

This final rule does not prohibit CRS or vehicle manufacturers from using the term LATCH (a term originally coined by industry and retail groups, not the agency). However, to help reduce potential confusion the agency will now require CRS and vehicle owner's manuals to include the standard terminology proposed in the NPRM when describing the components of the CRAS and its connectors.[153] This decision is being made based in part on over 15 years of consumer education efforts by the agency, manufacturers, and the safety community to clearly explain what the term LATCH means and to use it consistently. Given the ongoing confusion with this term, despite these ongoing efforts, it is clear consumers still struggle to understand the term. Although the standardized definitions required by this final rule will likely result in a transition period, with the need to inform parents and CPSTs about the terminology change, the new terminology will become commonplace and should assist in reducing current confusion.

NHTSA acknowledges UMTRI's statement that some of the confusion over the term LATCH stems from the requirement by NHTSA to refer to LATCH anchorages and connectors as the ''child restraint anchorage system.'' However, the term CRAS [154] is not widely used in owner's manuals or any education materials, but is instead mostly used in the FMVSS No. 213 required labels. Although the use of the term CRAS in FMVSS No. 213 may contribute to consumer confusion, the agency does not believe it is the predominant reason for the confusion as most other sources (such as manuals, voluntarily labels, education material, advertising material) typically use the term LATCH. Specifically, confusion is primarily created when referring to a LATCH installation because of different views on what the term means during everyday use. For example, to some consumers it may mean using the lower anchor installation, but not necessarily with the tether, as it may be a CRS that can be installed rear-facing where the tether is not used, or because they do not know that the tether should be used in a forward-facing CRS. To others, a LATCH installation may mean that the CRS is installed with the lower anchors and the tether. Therefore, under this understanding of the term, for CRSs that can be installed rear-facing (typically installed without a tether), a LATCH installation reference may not be appropriate.

NHTSA agrees with Graco's suggestion to update FMVSS No. 213 with the same terminology for lower anchorages and tether anchorage so that there is no confusion with how the labels will read versus the requirements in the NPRM, as the current regulatory text in FMVSS No. 213 calls for the use of child restraint anchorage systems in some instances. This final rule will update the required label text to reflect the new terminology proposed in the NPRM.[155] This decision also addresses UMTRI's comments regarding potential confusion over the term LATCH and child restraint anchorage systems in the required labeling text in FMVSS No. 213. NHTSA notes that in the standards' regulatory text, other than information presented to the consumer through labels or instruction manuals, the term anchorage will continue to be used, as it is part of the child restraint anchorage system. Further, as discussed below in the ''Housekeeping'' section of this final rule, the regulatory text required in FMVSS No. 225 that currently uses the term LATCH will be deleted from the standard per this final rule, as those sections are no longer active.

In response to UMTRI's suggestion to use the term ''LATCH belt'' instead of ''lower anchor strap,'' NHTSA disagrees with this suggestion, as the term ''strap'' is more often used when referring to the lower anchor strap and the agency has no information on whether the term ''belt'' instead of ''strap'' would have the effect of emphasizing that either the seatbelt or the LATCH belt are the primary means of attaching the CRS, as UMTRI expects. Further, FMVSS No. 213 & 213b standards currently have required labeling statements which use the word strap, so it would also promote consistency instead of introducing a different term. Finally, in response to UMTRI's recommendation to include required written instructions on how to use the V-tether straps and to use the tether with CRSs installed with seat belt, these comments are outside the scope of the NPRM's proposals and will therefore not be addressed as they fall outside the scope of this rulemaking.

d. Recommendation for Tether Anchorage Use Regardless of Child Weight

NHTSA requested comment on the merits of an instruction to consumers to use the tether to install all forward-facing child restraints with internal harnesses, whether installed with lower

[153] The NPRM proposed to add the term and definition of ''rigid lower anchor attachment'' (which means the child restraint system's lower anchorage connector that is rigid and does not have a lower anchorage strap), which also addresses comments recommending a standardized term.

[154] A ''child restraint anchorage system'' means a vehicle system that is designed for attaching a child restraint system to a vehicle at a particular designated seating position, consisting of two lower anchorages and a tether anchorage.

[155] The terminology proposed in the NPRM and adopted in this final rule is as follows: ''lower anchor(s)'' and ''tether anchor'' for components of the child restraint anchorage system, and ''lower anchor attachments'' and ''tether'' for components of the CRS that are used to connect the CRS to the vehicle. A ''lower anchor attachment'' is comprised of a ''lower anchor connector'' and a ''lower anchor strap'' (for flexible lower anchor attachments), and a ''tether'' is comprised of a ''tether hook'' and a ''tether strap.''

anchorages or seat belt, regardless of child weight.

The 2015 NPRM explained that a simple instruction would increase the ease-of-use of the tether, resulting in a decrease in injuries. The NPRM also presented data indicating that tether anchorages are already reasonably robust to withstand crash forces, and that the benefits of tether use for all children in the subject CRSs (regardless of child weight) outweigh the potential risks occurring from tether anchorage failure due to a higher combined weight and/or a higher severity crash.

Comments

Several commenters, including Graco, JPMA and UMTRI, supported the NPRM's recommendation that forward-facing CRSs should always be used with the tether. Graco agreed that the consumer should be advised to attach the tether when restraining a child in a harness CRS, regardless of the weight of the child. Graco explained that the limiting factor for structural strength is the CRS, which generally has a tether anchorage point in the plastic seat shell, and that crash energy dissipation can be had by the deformation of the plastic shell, reducing the energy going to the child while at the same time reducing the displacement of the child.

UMTRI stated that the potential benefits of the tether in a range of crashes far outweigh the hypothetical risks of injury due to a tether anchorage failure that has never been documented in a real-world crash and has only been demonstrated in a very small number of high-severity crash tests (less than 5).

Only one commenter, the Alliance, stated that it would be inappropriate for the agency to issue blanket instructions for consumers to use tethers with all children restrained in forward-facing CRS without providing some limits on both the child and CRS weight. The Alliance further explained that its members have differing opinions regarding use of tethers for child/CRS combinations in excess of 65 pounds based on internal testing and analysis conducted by each member company. The Alliance stated that when the current strength limits were developed for FMVSS No. 225, the agency made certain assumptions about the size and weight of the child/CRS combination, and that NHTSA originally considered a combined child and child restraint weight of 65 pounds when defining the strength requirements. The Alliance stated that its members agree that the 65 pounds combined weight limit is appropriate for child restraints secured with the lower and tether anchorages, but do not all agree that the same weight limit should be applied to a child restraint that uses a tether to supplement the seat belts for attachment.

The Alliance stated that the strength requirements specified in the current regulation are appropriate to assess anchorage strength in the regulation, since it is a repeatable test method and provides an appropriate design margin, given the rate-sensitive properties of the anchorages that result in increased load-carrying capabilities in real-world, short-duration crash pulses. However, the Alliance explained that the relationship between static and dynamic strength is dependent on the design of the system, including materials, geometry and attachment method. The Alliance added that the issue is further exacerbated by the lack of limits within FMVSS No. 213 on the size, weight, and capacity of the child restraints the anchorages are intended to restrain.

The Alliance further stated that while NHTSA references test data in the NPRM indicating many vehicles have tether anchorage strength that exceeds the FMVSS No. 225 regulatory static strength requirements, the agency has not tested every vehicle combination. The Alliance pointed out that while results from dynamic testing conducted by Transport Canada (referenced in the NPRM), are encouraging, this testing did not include all vehicle designs.

The Alliance stated it is well known that certain vehicles, based on their layout, have significant structure available to support tether anchorages, and thus might have a large compliance margin; however, the Alliance stated there may be vehicles which have to place the anchorages in locations with limited structural support. As a result, the Alliance explained that manufacturers may have to redesign those systems to add additional strength, which would impose additional cost and weight exceeding the values anticipated (and accepted by OMB) in the original rulemaking proposal. The Alliance added that tether anchorages located in the middle of seatbacks might have to move to the floor, pillars, or roof to meet higher loading requirements, conflicting with the goal to locate anchorages in uniform, easily accessible positions such as the center of the seatback.

The Alliance requested that if the agency does impose such a requirement for all vehicles, it must also impose a weight limit for CRSs, and/or require CRSs above a certain weight and designed for use by heavier children to include load limiting features on their tether anchorage attachment hardware. The Alliance also stated the new usage requirement must only apply to new vehicles, pointing out that it cannot be retroactive to all vehicles already in the field.

Agency Response

This final rule will implement the NPRM's proposal to develop simple education materials to promote the use of the tether when a tether and a tether anchorage are available. The agency made this decision following review of comments received. Most commenters, including JPMA, Graco, and UMTRI, expressed support for the NPRM's proposal to promote tether use by recommending its use in all forward-facing CRSs, whether installed using lower anchorages or seat belts, via a simple and uniform instruction.

Analysis of NHTSA's crash data files shows that the most common moderate to higher severity injuries among children restrained in rear seats are to the head and face and the most common contacts for these injuries to children are the seat and back support. Sled test data indicates that use of the upper tether reduces head excursions of the occupant restrained in the CRS and therefore, reduces the likelihood of head impacts against the vehicle structure.[156] Tether use may particularly benefit taller children since they may experience greater head excursion than children with shorter seated height.

The 2015 NPRM noted that 99.4 percent of crashes involving restrained children occur at change in velocities less than 30 mph and that for a majority of these crashes the loads on the tether anchor would be lower than the required strength per FMVSS No. 225, even if the child restraint and child combined weight exceeds 65 lb.[157] The NPRM noted that a forward-facing child restraint with tether attached would reduce the risk of head excursion and subsequent head contact and head injuries to the child in crashes with change in velocity less than 30 mph, which are the most common injury types to CRS restrained children.

[156] Legault, F. Garndner, B., Vincent, A., ''The Effect of Top Tether Strap Configurations on Child Restraint Performance,'' Society of Automotive Engineers, SAE No. 973304, 1997. In addition, the quantifiable safety benefits that NHTSA estimated will accrue from the LATCH rulemaking was due to the tether.

[157] FMVSS No. 225, ''Child restraint systems,'' established lower anchorage strength requirements developed to ensure that the vehicle child restraint anchorage system would be able to withstand forces resulting from a 65 lb mass in a severe crash of a vehicle into a rigid barrier.

The 2012 (77 FR 11626) [158] and 2014 (79 FR 10396) [159] final rules adopted labeling requirements into FMVSS No. 213, ''Child restraint systems,'' to inform the consumer when to stop installing a CRS using the lower anchorage attachments. These requirements consisted of calculating the maximum child weight a CRS could be used for when it is installed with the lower anchorages, based on the maximum combined weight (CRS weight + child weight) of 65 lb.

While the 2012 and 2014 final rules established a child weight limit for CRS lower anchorage installation, NHTSA did not adopt any requirements establishing a weight limit for tether use or issue any recommendations of tether use, as the agency needed more research to evaluate the potential benefits and risks. The tether supplements the primary attachment of the CRS to the vehicle seat (the primary attachment is accomplished by the lower anchorages of the child restraint anchorage system or by the vehicle seat belt). The primary attachment of the CRS to the vehicle should never fail in a crash since its integrity is needed to avoid a catastrophic uncoupling of the CRS from the vehicle.[160] The tether anchorage is a supplemental attachment point that enhances the safety of the CRS by reducing head excursions. Additionally, when the lower anchorages cannot be used to install a CRS due to the combined weight of the child and CRS exceeding the weight limit, the CRS can be installed using the vehicle's seat belt. However, even when the vehicle seat belt is used instead of the lower anchorages the tether anchorage should still be used.

As noted in the NPRM, crash test and quasi-static test data indicates that many tether anchorages in current vehicles can withstand the loads imparted in crashes up to 56 km/h by a CRS restraining 6-year-old and 10-year-old crash test dummies. These measured loads imparted to the tether anchorage represent the upper limit of expected tether anchorage loads in nearly all real-world crashes involving children restrained in CRSs. NHTSA has monitored field data for injuries resulting from tether anchorage failures due to excess loads in a crash and believes that such an event is very rare and any potential injury risk resulting from such an event is small.

NHTSA acknowledges the Alliance's comments expressing concerns over the NPRM's request for comment regarding consumer information to always use the tether for forward-facing CRSs regardless of child weight or attachment method (lower anchorages or seat belt). However, the organization did not provide any data suggesting the risk of tether anchorage failure outweighs any benefits of the use of the tether anchorage.

NHTSA disagrees with the Alliance's comments that (1) manufacturers would have to redesign some of their tether anchorage systems to support additional strength, which would impose additional cost and weight that would exceed the values anticipated in the original rulemaking proposal; and (2) the requirement cannot be retroactive to all vehicles already in the field. The agency is not requiring vehicle manufacturers to comply with a higher strength requirement on the tether anchorages. Instead, NHTSA is recommending consumers always use a tether (when available in CRS and vehicle seating position) when installing forward-facing CRSs to enhance the safety of all children in CRSs. Further, the required label on the CRS specifying the child and CRS weight limit only applies to the use of the lower anchorages for installing the CRS in the vehicle. This combined child and CRS weight limit does not apply to the use of tether anchorages when the CRS is installed using seat belts or the lower anchorages.

NHTSA is aware that since the publication of the 2012 final rule some vehicle manufacturers have applied the lower anchorage weight limit to the tether anchorages or to the full child restraint anchorage system (lower anchorages and tether) in the vehicle owner's manual. However, NHTSA points out that the 2012 final rule did not impose any child weight restrictions for the use of the tether anchorages.

The agency believes that the increased use of tethers expected from these uniform and simple instructions will help minimize injuries in most crashes involving children where the loads to the tether would be within the required strength requirements. Specifically, a single consistent statement will promote tether use.[161] Therefore, the agency's recommendation for best protection is to always use the tether when installing a forward-facing CRS.

X. Housekeeping

Section 5(c) of the FMVSS No. 225 current standard has sections that refer to requirements for vehicles with an air bag on-off switch. However, the air bag on-off switch requirements in Section 4.5.4 of FMVSS No. 208; ''Occupant crash protection,'' ceased to be in effect on September 1, 2012, and, therefore, are no longer available in production vehicles.[162] As such, this final rule is revising section 5(c) to remove the obsolete requirements.

XI. Lead Time and Phase-In

In the 2015 NPRM, NHTSA proposed a compliance date [163] 3 years after the final rule is published. NHTSA noted 3 years would provide sufficient time for vehicle manufacturers to accommodate any redesign of the vehicle seat in their normal course of vehicle design cycles without a cost increase. Additionally, the agency considered the 3-year lead time sufficient for child restraint manufacturers to comply with the proposed tether hardware length limit.

Comments on Lead Time for Vehicles

Global, Ford, Toyota, Alliance, FCA, and Honda stated that the proposed lead time was insufficient. The commenters provided several reasons in support of a longer lead time, including that design changes needed to meet the proposed requirements would involve significant design changes, body structure reinforcement and re-design, changes to tether anchorage markings on plastic base/cover, changes to the seat and anchorages, and, in some cases, development of new attachment schemes.

Global and Toyota commented on the need to redesign the package shelf, located behind the rearmost row of seats. Global and Toyota stated that package shelf speakers would need to be relocated to accommodate the tether anchorage beyond the 165-mm proposed requirement. Global stated that center

[158] In the 2012 final rule the CRS was required to have the statement: ''Do not use the lower anchors of the child restraint anchorage system (LATCH system) to attach this child restraint when restraining a child weighing more than _*_with internal harness of the child restraint,'' where ''*'' is a value where the sum of the recommended child weight and the weight of the child restraint system do not exceed 65 pounds (29.5 kg).

[159] In the 2014 final rule the CRS was required to have an installation diagram of the CRS using the lower anchorages with the statement ''Do not install by this method for a child weighing more than _*_,'' where ''*'' is the child weight limit in accordance with tables described in the standard. The tables were based on a 65 lb combined weight but give some allowances to allow manufacturers to round the child weight limit and maximize lower anchorage use.

[160] Thus, the combined weight of CRS + child should not exceed 29.5 kg (65 lb) on the lower anchorages.

[161] Research indicates that only about half of vehicle owners read their owner's manual.

[162] On September 17, 2024, the agency published an NPRM (89 FR 76035) proposing to remove the *retrofit* air bag on-off switch sunset date. The agency is not removing the sunset of air bag on-off switches in production vehicles.

[163] Compliance date is the date by which manufacturers must demonstrate adherence to the regulation. Effective date is the date when the CFR is amended by following the instructions in a final rule.

seating positions in second and third rows would implicate significant design changes. Ford indicated that these changes would require design and tooling changes outside the normal product design cycle.

Commenters proposed adding a phased schedule for all new vehicle models to meet the new requirements, lasting from two to four years. Specifically, Global suggested a compliance date four years after the date of final rule publication, followed by an additional two-year phase-in period for each manufacturer to achieve 100 percent compliance. Toyota suggested delaying start of compliance at least four years from the September 1 following the publication of the final rule, followed by a three-year phase-in period. Under Toyota's phase-in schedule, twenty percent of a manufacturer's vehicles would need to comply the first year, fifty percent the second year, and one hundred percent in the final year, similar to what was used in the rulemaking for FMVSS No. 225 in 1999. FCA requested a three-year compliance date followed by four-year phase-in, with credits permitted. Honda recommended a three-year effective date followed by a three-year phase-in with percentages equal to Toyota's proposal.

Toyota and the Alliance stated that the compliance dates should not deviate from September 1 (typical MY changeover). FCA remarked that a longer lead time would reduce the overall cost and not cause significant delays in a vehicle program.

Agency Response

The NPRM proposed a 3-year lead time to provide sufficient time for vehicle manufacturers to accommodate any redesign of the vehicle seat in their normal course of manufacture without a cost increase. However, the agency acknowledges multiple NPRM comments indicating that significant design changes, such as body structure reinforcement and re-design, changes to the seat and anchorages, and, in some cases, development of new attachment schemes, would be necessary to meet the proposed requirements. Based on these concerns, several commenters indicated the need for significantly more time than the proposed 3-year lead time to redesign their vehicles to meet the proposed rule. After full consideration of the comments received, NHTSA agrees with the request for a longer compliance lead time followed by a phase-in period for vehicle requirements.

When FMVSS No. 225 was introduced, the final rule contained a compliance phase-in for the tether anchorages that started 1.5 years after the rule was published and 2.5 years for the lower anchorages.[164] In response to petitions for reconsideration of that final rule, the agency granted extensions and temporary alternative options to comply with the standard. Based on the changes proposed in this final rule, a 3-year phase-in schedule that begins at least three years after the publication of the final rule should provide manufacturers with similar relief as the schedule that took place with the adoption of FMVSS No. 225. The 3-year phase-in will begin on the first September 1 that is 3 years after publication of the final rule. In the first year of the phase-in, a minimum of 20 percent of each manufacturer's applicable vehicles produced during that 1-year period will be required to meet the updated standard, followed by 50 percent of the applicable vehicle production in the second year, and 100 percent of applicable vehicle production in the third year and later.

Providing a 3-year phase-in period for complying with the final rule, following a lead time of at least 3 years, will provide sufficient time for vehicle manufacturers to accommodate any redesign of the vehicle seat, rear shelf structures, and other components in the vehicle in their normal course of design and manufacture without a cost increase.

NHTSA will remove the exceptions in current S5(a) and S5(e) as discussed in section VIII of this final rule starting on the first September 1 that is six years after publication of the final rule. After this date convertible vehicles will be required to be equipped with tether anchorages, and all applicable vehicles, with no exceptions, will be required to provide lower anchorages. This lead time will give manufacturers time to update their vehicle designs within their design cycles and potentially incorporate the change within the same cycle as the rest of the requirements.

Comments on Lead Time for CRSs

In response to the proposed 3-year lead time for CRSs, Britax and JPMA stated that a three-year implementation period from the adoption of a final rule is necessary to make tooling changes for the metal components of the tether anchorages and/or to ensure that tethers in CRSs are assembled with tags displaying this symbol as well as to facilitate incorporating the revisions to CRS printed materials.

Dorel agreed that 3 years is sufficient lead time to meet the proposed FMVSS No. 213 requirements. Dorel asked that an early compliance option to the new standard be available from the date of publication of the final rule for both vehicle and CRS manufacturers to further incentivize early compliance and ease-of-use claims to the new standard.

The agency did not receive comments in opposition to the proposed lead time for CRS requirement updates.

Agency Response

This final rule provides a 3-year lead time with no phase-in period for CRS manufacturers, as proposed, to give enough time to redesign, make tooling changes, and include markings.

XII. Cost Benefit Analysis

The agency estimates that the adopted requirements for improved usability of CRASs would not result in any increase in material cost but would entail some redesign of vehicle seat features. Approximately 79 percent of vehicles would need some redesign to meet the proposed lower anchorage usability requirements. Some lower anchorages would need to be repositioned or the trim and structures around them modified to meet the clearance angle and lower anchorage depth requirements adopted in this final rule. Some tether anchorages would have to be repositioned farther from the head restraint to meet the minimum strap wrap-around distance requirement. Based on feedback received, this final rule is providing a 3-year phase-in period following a 3-year lead time that starts on the first September 1 after the publication of the final rule, for manufacturers to comply with the final rule. This lead time will provide sufficient time for vehicle manufacturers to accommodate any needed redesign of the vehicle seat and rear shelf structures into their normal course of design and manufacture, without a cost increase.

For child restraints, the agency estimates that approximately 30 percent of forward-facing child restraints may need minor modification to the tether hardware assembly to meet the 165 mm (6.5 in) maximum length requirement, such as changing the supplier to other available tether hardware models. Minimal or no costs are expected from this change as many available tether designs are available in the market.

In relation to this final rule's requirement that all lower anchorages and tether anchorages must be marked with the ISO symbol, we estimate the cost of ISO markings for a set of lower

[164] The final rule was published in March 1999 and the phase-in period for the tether was September 1, 1999, through September 1, 2000. For the lower anchorages, the phase-in period was September 1, 2000, through September 1, 2002.

anchorages to be $0.07 and that for the tether anchorage to be $0.03. The total incremental estimated cost of equipping all CRASs with appropriate ISO markings is approximately $0.76 million. The final rule also requires similar ISO markings on child restraint anchorage connectors, for which the agency estimates an incremental cost of $0.97 million. The cost of changing the written instructions accompanying the vehicle or the CRS to explain the ISO markings is expected to be negligible (less than $0.01). Therefore, the total cost of the final rule is estimated to be $1.73 million.

In relation to the benefits of this proposed rule, the new usability requirements will improve correct (tight) installation and increase tether use. If the changes required by this final rule provide a 5 percent increase in correct installation using the lower anchorages and a 5 percent increase in tether use, the agency estimates that the proposed requirements would save approximately 3 lives and prevent 6 moderate to higher severity injuries annually.

XIII. Regulatory Notices and Analyses

Executive Order 12866, Executive Order 14904, Executive Order 13563, and DOT Regulatory Policies and Procedures

NHTSA has considered the potential impact of this final rule under Executive Order 12866, Executive Order 14094, Executive Order 13563, DOT Order 2100.6A, and the Department of Transportation's regulatory policies and procedures. This final rule is not considered to be significant under the Department of Transportation's regulatory policies and procedures.[165]

This final rule makes several changes to FMVSS No. 225 and FMVSS No. 213b by specifying additional requirements for CRAS and CRSs to improve ease-of-use of CRAS and improve the likelihood that CRSs will be correctly used in vehicles. The agency estimates that the adopted requirements for improved usability of CRASs would not result in any increase in material cost but would entail some redesign of vehicle seat features.

Specifically, NHTSA is providing a 3-year phase-in period following a 3-year lead time that starts on the first September 1 after the publication of the final rule for complying with the final rule. We believe this lead-time and phase-in schedule will provide sufficient time for vehicle manufacturers to accommodate any redesign of the vehicle seat and rear shelf structures into their normal course of design and manufacture without increased cost. NHTSA is also providing an additional 3-year lead time for removing some exclusions for providing lower anchorages and tether anchorages in some vehicles. We estimate a total cost of $1.73 million for the requirements for markings to identify and locate CRAS in vehicles.

More information can be found in the ''Cost Benefit Analysis'' section above. The minimal impacts of this final rule did not warrant the preparation of a regulatory evaluation.

Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.,* as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an 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 governmental jurisdictions). The Small Business Administration's regulations at 13 CFR part 121 define a small business, in part, as a business entity ''which operates primarily within the United States.'' (13 CFR 121.105(a)). No regulatory flexibility analysis is required if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The 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. NHTSA has evaluated the effects of this action on small entities.

I hereby certify that this final rule will not have a significant economic impact on a substantial number of small entities. This final rule specifies additional requirements for CRAS and CRSs to improve ease-of-use of CRAS and to improve the likelihood that CRSs will be correctly used in vehicles. The final rule provides a 3-year lead start time, followed by a 3-year phase-in period for complying with the final rule that would provide sufficient time for small manufacturers to modify designs within normal design cycles, and thereby not incur additional manufacturing costs.

NHTSA estimates there are 38 manufacturers of child restraints, none of which are small businesses. Even if there were a small CRS manufacturer, the impacts of this proposed rule would not be significant. This final rule adopts minor changes to the requirements applying to CRSs. The requirements are: Limiting the length of the tether hardware assembly (tether hook and tightening mechanism) to 165 mm (6.5 in) (UMTRI estimated that about 30 percent of CRS models might need some changes to the tether hardware assembly to meet the 165 mm (6.5 in) limit), marking the lower anchorage connectors and the tether hook or tether strap with the ISO marking, and changing written instructions provided to the owners to include the defined terms and instruction on using the tether. These are minor changes that do not affect the shell or any other structure of the child restraint. We believe that there would be no incremental cost due to limiting the tether hardware assembly to 165 mm (6.5 in) since the tether hardware assembly costs would not increase because of the requirement. We estimate that the cost of marking the CRS child restraint anchorage connectors would be about $0.07 per set of lower anchorage connectors and $0.04 per tether hook. Changing the written instructions accompanying CRSs would be negligible (significantly less than $0.01).

NHTSA is aware of six vehicle manufacturers that may be categorized as small businesses. However, the proposed rule will not have a significant economic impact on these manufacturers, as vehicles produced by these small manufacturers already have to provide child restraint anchorage systems and tether anchorages meeting FMVSS No. 225, unless the vehicle is excluded from the standard. The changes proposed in this NPRM only adjust the physical features of the anchorage systems, adjustments which should have a positive impact on the ease of use of the systems, but that are small in terms of affecting the overall configuration of current anchorage systems. We estimate the cost of marking the lower anchorages and the tether anchorages to be less than approximately $0.16 (depending on the number of anchorages in the vehicle) per vehicle. The cost of changing the written instructions accompanying the vehicle would be negligible, less than $0.01.

This rule may also affect final stage manufacturers and alterers, many of whom would be small businesses. However, NHTSA believes that the impacts of this final rule on such entities would not be significant. Final-stage manufacturers or alterers installing rear seats in vehicles subject to FMVSS No. 225 must already provide child restraint anchorage systems and tether anchorages meeting FMVSS No. 225.

[165] 44 FR 11034 (Feb. 26, 1979).

We believe that the changes adopted in this final rule only make small adjustments to the physical features of the anchorage systems, adjustments that should have a positive impact on the ease of use of the systems, but that are minor in terms of the impact on the configuration of current anchorage systems. We estimate the cost of marking the lower anchorages and the tether anchorages would be less than $0.16 per vehicle (depending on the number of anchorages in the vehicle). The cost of changing the written instructions accompanying the vehicle would be negligible (significantly less than $0.01 per vehicle).

Federalism

NHTSA has examined this final rule pursuant to E.O. 13132 (64 FR 43255, August 10, 1999) and concluded that no additional consultation with states, local governments, or their representatives is mandated beyond the rulemaking process. The agency has concluded that the rulemaking would not have sufficient federalism implications to warrant consultation with state and local officials or the preparation of a federalism summary impact statement. This final rule would 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.''

NHTSA rules can have a preemptive effect in two ways. First, the National Traffic and Motor Vehicle Safety Act contains an express preemption provision: When a motor vehicle safety standard is in effect under this chapter, a state or a political subdivision of a state may prescribe or continue in effect a standard applicable to the same aspect of performance of a motor vehicle or motor vehicle equipment only if the standard is identical to the standard prescribed under this chapter. 49 U.S.C. 30103(b)(1). It is this statutory command by Congress that preempts any non-identical state legislative and administrative law address the same aspect of performance.

The express preemption provision described above is subject to a savings clause under which ''[c]ompliance with a motor vehicle safety standard prescribed under this chapter does not exempt a person from liability at common law.'' 49 U.S.C. 30103(e). Pursuant to this provision, state common law tort causes of action against motor vehicle manufacturers that might otherwise be preempted by the express preemption provision are generally preserved.

NHTSA rules can also preempt state law if complying with the FMVSS would render the motor vehicle manufacturers liable under state tort law. Because most NHTSA standards established by an FMVSS are minimum standards, a state common law tort cause of action that seeks to impose a higher standard on motor vehicle manufacturers will generally not be preempted. However, if and when such a conflict does exist—for example, when the standard at issue is both a minimum and a maximum standard—the state common law tort cause of action is impliedly preempted. *See Geier* v. *American Honda Motor Co., 529 U.S. 861 (2000).*

Pursuant to E.O. 13132, NHTSA has considered whether this final rule could or should preempt state common law causes of action. The agency's ability to announce its conclusion regarding the preemptive effect of one of its rules reduces the likelihood that preemption will be an issue in any subsequent tort litigation. To this end, the agency has examined the nature (*e.g.,* the language and structure of the regulatory text) and objectives of this final rule and finds that this final rule, like many NHTSA rules, prescribes only a minimum safety standard.

Accordingly, NHTSA does not intend that this final rule preempt state tort law that would effectively impose a higher standard on motor vehicle manufacturers than that established by this final rule. Establishment of a higher standard by means of state tort law would not conflict with the minimum standard finalized in this document. Without any conflict, there could not be any implied preemption of a state common law tort cause of action.

National Environmental Policy Act

NHTSA has analyzed this rule for the purposes of the National Environmental Policy Act. In accordance with 49 CFR 1.81, 42 U.S.C. 4336, and DOT NEPA Order 5610.1C, NHTSA has determined that this rule is categorically excluded pursuant to 23 CFR 771.118(c)(4), (planning and administrative activities, such as promulgation of rules, that do not involve or lead directly to construction). This rulemaking, which amends Federal Motor Vehicle Safety Standard (FMVSS) No. 225, ''Child Restraint Anchorage Systems,'' and FMVSS No. 213b, ''Child Restraint Systems,'' to improve ease-of-use of the lower and tether anchorages, improve correct use of child restraint systems in vehicles, and maintain or improve the correct use and effectiveness of child restraint systems (CRSs) in motor vehicles, is not anticipated to result in any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

Paperwork Reduction Act (PRA)

Under the procedures established by the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501, *et seq.*), a Federal agency must request and receive approval from the Office of Management and Budget (OMB) before it collects certain information from the public and a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid OMB control number. This rulemaking creates new information collection requirements for phase-in reporting and record retention requirements.

In compliance with the requirements of the PRA, NHTSA is separately publishing a document requesting comment on NHTSA's intention to request approval for a new information collection request. Specifically, NHTSA is requesting approval for a new information collection that would require manufacturers of passenger cars and trucks and multipurpose passenger vehicles with a GVWR or 3,855 kg (8,500 lb) or less and buses with a GVWR of 4,536 kg (10,000 lb) or less to annually submit a report, and maintain records related to the report, concerning the number of such vehicles that meet the child restraint anchorage system requirements of FMVSS No. 225 during the phase-in of those requirements.

The phase-in of the requirements would be completed approximately 6 years after publication of the final rule. The purpose of the reporting requirements is to aid the agency in determining whether a manufacturer of passenger cars and trucks and multipurpose passenger vehicles with a GVWR of 3,855 kg (8,500 lb) or less, or buses with a GVWR of 4,536 kg (10,000 lb) or less, has complied with the child restraint anchorage system requirements during the phase-in of those requirements.

NHTSA estimates this collection will impact 22 manufacturers each year and will have a total annual burden of approximately 22 hours and $0 non-labor costs.

Unfunded Mandates Reform Act (UMRA)

The Unfunded Mandates Reform Act of 1995 (UMRA) requires Federal agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by state, local, or tribal

governments, in the aggregate, or by the private sector, of more than $100 million annually (adjusted annually for inflation, with base year of 1995). UMRA also requires an agency issuing an NPRM or final rule subject to the Act to select the ''least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule.'' This final rule would not result in a Federal mandate that will likely result in the expenditure by state, local, or tribal governments, in the aggregate, or by the private sector, of more than $100 million annually (adjusted annually for inflation, with base year of 1995).

Executive Order 12988 (Civil Justice Reform)

With respect to the review of the promulgation of a new regulation, section 3(b) of Executive Order 12988, ''Civil Justice Reform'' (61 FR 4729, Feb. 7, 1996), requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect; (2) clearly specifies the effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct, while promoting simplification and burden reduction; (4) clearly 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. This document is consistent with that requirement.

Pursuant to this Order, NHTSA notes as follows. The issue of preemption is discussed above. NHTSA notes further that there is no requirement that individuals submit a petition for reconsideration or pursue other administrative proceedings before they may file suit in court.

Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. NHTSA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule does not meet the criteria in 5 U.S.C. 804(2) to be considered a major rule. The rule will be effective sixty days after the date of publication in the **Federal Register**.

National Technology Transfer and Advancement Act

Under the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Pub. L. 104–113), all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments. Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies, such as the International Organization for Standardization (ISO) and the Society of Automotive Engineers (SAE). The NTTAA directs this agency to provide Congress, through OMB, explanations when we decide not to use available and applicable voluntary consensus standards. There are no voluntary consensus standards developed by voluntary consensus standards bodies pertaining to this final rule.

Plain Language Requirement

Executive Order 12866 requires each agency to write all rules in plain language. Application of the principles of plain language includes consideration of the following questions:

- Have we organized the material to suit the public's needs?
- Are the requirements in the rule clearly stated?
- Does the rule contain technical language or jargon that isn't clear?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the rule easier to understand?
- Would more (but shorter) sections be better?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rule easier to understand?

NHTSA has considered these questions and attempted to use plain language in promulgating this final rule. If readers have suggestions on how we can improve our use of plain language, please write us.

Regulatory Identifier Number (RIN)

The DOT assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading at the beginning of this document may be used to find this action in the Unified Agenda.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its decision-making process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.transportation.gov/privacy.* Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

Incorporation by Reference

Updates to FMVSS No. 225 (49 CFR 571.225) in this final rule include new requirements to evaluate the lower anchorage depth and clearance angle using new tools. NHTSA incorporates by reference two drawing packages, with detailed drawings of the tools used to measure these new requirements, into FMVSS No. 225 (49 CFR 571.225). The drawing packages are titled, *Anchorage Depth Tool,* dated April 2020, and *Clearance Angle Tool,* dated April 2020. Interested persons may use the drawing package to manufacture the standard seat assembly for their own use if they wish to do so.

NHTSA has placed a copy of the material in the docket for this final rule. Interested persons can download a copy of the material or view the material online by accessing *www.regulations.gov,* phone 1–877–378–5457, or by contacting NHTSA's Chief Counsel's Office at the phone number and address set forth in the **FOR FURTHER INFORMATION CONTACT** section of this document. The material is also available for inspection at the Department of Transportation, Docket Operations, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC; phone: 202–366–9826.

Regulatory Text

List of Subjects

49 CFR Part 571

Imports, Incorporation by Reference, Motor vehicle safety, Motor vehicles, Tires.

49 CFR Part 585

Reporting and recordkeeping requirements

In consideration of the foregoing, NHTSA amends 49 CFR part 571 as set forth below.

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

■ 1. The authority citation for part 571 continues to read as follows:

Authority: 49 U.S.C. 322, 30111, 30115, 30117 and 30166; delegation of authority at 49 CFR 1.95.

■ 2. Section 571.5 is amended by adding paragraphs (k)(10) and (11) to read as follows:

§ 571.5 Matter incorporated by reference.

* * * * *

(k) * * *

(10) Drawing Package, *Anchorage Depth Tool,* dated April 2020; approved for § 571.225.

(11) Drawing Package, *Clearance Angle Tool,* dated April 2020; approved for § 571.225.

* * * * *

■ 3. Section 571.213b is amended by:
■ a. Revising S5.5.2(j);
■ b. Adding S5.6.1.13 and S5.6.1.14;
■ c. Revising S5.9(a) through (c); and
■ d. Adding figures 15 and 16.

The revisions and additions read as follows:

§ 571.213b Child restraint systems; Mandatory applicability beginning December 5, 2026.

* * * * *

S5.5.2 * * *

(j) In the case of each child restraint system equipped with a tether strap the statement: Secure the tether strap provided with this child restraint.

* * * * *

S5.6.1.13 In the case of child restraint systems marked as specified in S5.9(a) and (b) of this standard, explain that the markings identify the lower anchor connectors and the tether anchor connector, respectively, and that the consumer should look for corresponding marks on the vehicle child restraint anchorage system to attach the appropriate connectors of the child restraint system.

S5.6.1.14 Use the following terms when referring to the different components of the child restraint anchorage system or for components of the child restraint system that are used to connect the child restraint system to the vehicle: ''lower anchor'' means the lower anchorage of the child restraint anchorage system in the vehicle, ''tether anchor'' means the top tether anchorage of the child restraint anchorage system in the vehicle, ''lower anchor attachment'' means the child restraint system or the detachable base's (in the case of a rear-facing child restraint with a detachable base) lower anchorage connector and the lower anchorage strap (for flexible lower anchorage attachments), ''rigid lower anchor attachment'' means the child restraint system or the detachable base's (in the case of a rear-facing child restraint with a detachable base) lower anchorage connector that is rigidly attached to the CRS and does not have a lower anchorage strap, and ''tether'' means the child restraints system's tether hook and tether strap.

* * * * *

S5.9 * * *

(a) Each add-on child restraint system other than a car bed, harness, or belt-positioning seat shall have components permanently attached to the system that enable the restraint to be securely fastened to the lower anchorages of the child restraint anchorage system specified in Standard No. 225 (§ 571.225) and depicted in NHTSA Standard Seat Assembly; FMVSS No. 213, No. NHTSA–213–2021, (March 2023) (incorporated by reference, *see* § 571.5). The components must be attached to the add-on child restraint by use of a tool, such as a screwdriver. In the case of rear-facing child restraints with detachable bases, only the base is required to have the components. All components provided to attach the add-on child restraint or the detachable base (in the case of a rear-facing child restraint with a detachable base) to the lower anchorages of the child restraint anchorage system shall be permanently marked with the pictogram in figure 15 to this section.

(b) In the case of each child restraint system that has components for attaching the system to a tether anchorage, those components shall include a tether hook that conforms to the configuration and geometry specified in figure 11 to this section. The tether hook or the tether strap shall be permanently marked with either pictogram shown in figure 16 to this section. If the mark is on the tether strap or on a tag attached to the tether strap, the mark must be located within 25 mm of the tether hardware assembly (which consists of a tether hook and a webbing tightening mechanism designed to tighten or loosen the tether strap).

(c) In the case of each child restraint system that has components, including belt webbing, for attaching the system to an anchorage of a child restraint anchorage system (lower anchorage or tether anchorage), the belt webbing shall be adjustable so that the child restraint can be tightly attached to the vehicle. The length of the tether hardware assembly, which consists of a tether hook and a mechanism designed to tighten and loosen the tether strap, shall not exceed 165 mm.

* * * * *

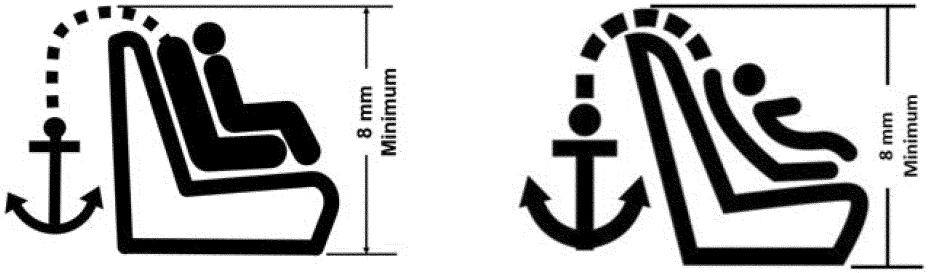
Figure 15 to § 571.213b—Lower Anchorage Connector Symbol

Note 1 to Figure 15 to § 571.213b: Drawing not to scale.

Note 2 to Figure 15 to § 571.213b: Symbol may be shown in mirror image.

Note 3 to Figure 15 to § 571.213b: Color of the symbol is at the option of the manufacturer.

Figure 16 to § 571.213b—Tether Anchorage Connector Symbols



Note 1 to Figure 16 to § 571.213b: Drawing not to scale.

Note 2 to Figure 16 to § 571.213b: Symbol may be shown in mirror image.

Note 3 to Figure 16 to § 571.213b: Color of the symbol is at the option of the manufacturer.

Note 4 to Figure 16 to § 571.213b: Either symbol may be marked at the option of the manufacturer.

■ 4. Section 571.225 is amended by:
■ a. Revising S4.2;
■ b. Removing S4.3, S4.4, and S4.5;
■ c. Redesignating S4.6 as S4.3 and revising it;
■ d. Revising S5 and S6;
■ e. Revising the first sentence of S8 introductory text and revising S8.1 introductory text;
■ f. Removing and reserving S8.2;
■ g. Revising S9 introductory text and S9.1.1(d) and S9.2;
■ h. Adding S9.2.4 and S9.2.5;
■ i. Revising S9.5;
■ j. Revising S11, S12, and S13;
■ k. Removing S14, S15, and S16;
■ l. Revising figures 8, 9, 10, and 19, removing and reserving figure 11, and adding figures 23 through 28.

The revisions and additions read as follows:

§ 571.225 Child restraint anchorage systems.

* * * * *

S4.2 Vehicles shall be equipped as specified in paragraphs S4.2(a) through (c), except as provided in S5 of this standard.

(a) Each vehicle with three or more forward-facing rear designated seating positions shall be equipped as specified in S4.2(a)(1) and (2).

(1) Each vehicle shall be equipped with a child restraint anchorage system conforming to the requirements of S6 and S9 of this standard at not fewer than two forward-facing rear designated seating positions. At least one of the child restraint anchorage systems shall be installed at a forward-facing seating position in the second row in each vehicle that has three or more rows, if such a forward-facing seating position is available in that row.

(2) Each vehicle shall be equipped with a tether anchorage conforming to the requirements of S6 of this standard at a third forward-facing rear designated seating position. The tether anchorage of a child restraint anchorage system may count towards the third required tether anchorage. In each vehicle with a forward-facing rear designated seating position other than an outboard designated seating position, at least one tether anchorage (with or without the lower anchorages of a child restraint anchorage system) shall be at such a designated seating position.

(b) Each vehicle with not more than two forward-facing rear designated seating positions shall be equipped with a child restraint anchorage system conforming to the requirements of S6 and S9 of this standard at each forward-facing rear designated seating position.

(c) Each vehicle without any forward-facing rear designated seating position shall be equipped with a tether

anchorage conforming to the requirements of S6 of this standard at each forward-facing front passenger designated seating position.

S4.3 *Movable seats.* (a) A vehicle that is equipped with a forward-facing rear designated seating position that can be moved such that it is capable of being used at either an outboard or non-outboard forward-facing designated seating position shall be considered as having a forward-facing non-outboard designated seating position. Such a movable seat must be equipped with a tether anchorage that meets the requirements of S6 of this standard or a child restraint anchorage system that meets the requirements of S6 and S9 of this standard, if the vehicle does not have another forward-facing non-outboard designated seating position that is so equipped.

(b) Tether and lower anchorages shall be available for use at all times, except when the seating position for which it is installed is not available for use because the vehicle seat has been removed or converted to an alternate use such as allowing for the carrying of cargo.

S5 *General exceptions.* Vehicles manufactured before September 1, 2031, must meet the requirements of S5.1. Vehicles manufactured on or after September 1, 2031, must meet the requirements of S5.2.

S5.1 *Vehicles manufactured before September 1, 2031.* (a) Convertibles and school buses are excluded from the requirements to be equipped with tether anchorages.

(b) A vehicle may be equipped with a built-in child restraint system conforming to the requirements of Standard No. 213 (§ 571.213) or Standard No. 213b (§ 571.213b) as applicable, instead of one of the required tether anchorages or child restraint anchorage systems.

(c) Vehicles with no air bag in front passenger designated position:

(1) Each vehicle that does not have a rear designated seating position and does not have an air bag installed at front passenger designated seating positions pursuant to a temporary exemption granted by NHTSA under 49 CFR part 555, must have a child restraint anchorage system installed at a front passenger designated seating position. In the case of convertibles, the front designated passenger seating position need have only the two lower anchorages meeting the requirements of S9 of this standard.

(2) Each vehicle that has a rear designated seating position and meets the conditions in S4.5.4.1(b) of Standard No. 208 (§ 571.208), and does not have an air bag installed at front passenger designated seating positions pursuant to a temporary exemption granted by NHTSA under 49 CFR part 555, must have a child restraint anchorage system installed at a front passenger designated seating position in place of one of the child restraint anchorage systems that is required for the rear seat. In the case of convertibles, the front designated passenger seating position need have only the two lower anchorages meeting the requirements of S9 of this standard.

(d) A vehicle that does not have an air bag on-off switch meeting the requirements of S4.5.4 of Standard No. 208 (§ 571.208) shall not have any child restraint anchorage system installed at a front designated seating position.

(e) A vehicle with a rear designated seating position for which interference with transmission and/or suspension components prevents the location of the lower bars of a child restraint anchorage system anywhere within the zone described by S9.2 of this standard is excluded from the requirement to provide a child restraint anchorage system at that position. However, except as provided elsewhere in this S5, such a vehicle must have a tether anchorage at a front passenger designated seating position.

S5.2 *Vehicles manufactured on or after September 1, 2031.* (a) School buses are excluded from the requirements to be equipped with tether anchorages.

(b) A vehicle may be equipped with a built-in child restraint system conforming to the requirements of Standard No. 213b (§ 571.213b) instead of one of the required tether anchorages or child restraint anchorage systems.

(c) Vehicles with no air bag in front passenger designated position:

(1) Each vehicle that does not have a rear designated seating position and does not have an air bag installed at front passenger designated seating positions pursuant to a temporary exemption granted by NHTSA under 49 CFR part 555 must have a child restraint anchorage system installed at a front passenger designated seating position.

(2) Each vehicle that has a rear designated seating position and meets the conditions in S4.5.4.1(b) of Standard No. 208 (§ 571.208), and does not have an air bag installed at front passenger designated seating positions pursuant to a temporary exemption granted by NHTSA under 49 CFR part 555, must have a child restraint anchorage system installed at a front passenger designated seating position in place of one of the child restraint anchorage systems that is required for the rear seat.

(d) A vehicle that does not have an air bag on-off switch meeting the requirements of S4.5.4 of Standard No. 208 (§ 571.208), shall not have any child restraint anchorage system installed at a front designated seating position.

S6. *Requirements for tether anchorages.* Vehicles subject to Standard No. 225 (this section) shall meet the tether anchorage requirements specified in S6.1, S6.2, and S6.4 according to the phase-in schedule specified in S13 of this standard.

S6.1 *Configuration of the tether anchorage.*

S6.1.1 Each tether anchorage shall:

(a) Permit the attachment of a tether hook of a child restraint system meeting the configuration and geometry specified in figure 11 of Standard No. 213 (figure 11 to § 571.213);

(b) Be accessible without the need for any tools other than a screwdriver or coin;

(c) Once accessed, be ready for use without the need for any tools; and

(d) Be sealed to prevent the entry of exhaust fumes into the passenger compartment.

S6.1.2 Each tether anchorage shall:

(a) Consist of a rigid bar of any cross-section shape that permits the attachment of a tether hook (of a child restraint system) meeting the configuration and geometry specified in figure 11 of Standard No. 213 (figure 11 to § 571.213), except in buses with a GVWR less than or equal to 10,000 pounds and vehicles that use a routing device per S6.2.1.2;

(b) Be accessible without the need for any tools and without folding the seat back (other than the head restraint) or removing carpet or other vehicle components (other than cargo covers) to access the anchorages. Individual tether anchorages may be covered with a cap, flap, or cover, provided that any cap, flap, or, cover is specifically designed to be opened, moved aside, or to otherwise give unobstructed access to the anchorage and is labeled with the symbol shown in figure 25 to this section;

(c) Once accessed, be ready for use without the need for any tools; and

(d) Be sealed to prevent the entry of exhaust fumes into the passenger compartment.

S6.2 *Location of the tether anchorage.*

S6.2.1 Subject to S6.2.1.2, the part of each tether anchorage that attaches to a tether hook must be located within the shaded zone shown in figures 3 through 7 to this section of the designated seating position for which it is installed. The zone is defined with reference to the seating reference point (*see* § 571.3).

(For purposes of the figures, ''H Point'' is defined to mean seating reference point.) A tether anchorage may be recessed in the seat back, provided that it is not in the strap wrap-around area at the top of the vehicle seat back. For the area under the vehicle seat, the forwardmost edge of the shaded zone is defined by the torso line reference plane.

S6.2.1.1 [Reserved]

S6.2.1.2 In the case of a vehicle that—

(a) Has a user-ready tether anchorage for which no part of the shaded zone shown in Figures 3 to 7 of this standard of the designated seating position for which the anchorage is installed is accessible without removing a seating component of the vehicle; and

(b) Has a tether strap routing device that is—

(1) Not less than 65 mm behind the torso line for that seating position, in the case of a flexible routing device or a deployable routing device, measured horizontally and in a vertical longitudinal plane; or

(2) Not less than 100 mm behind the torso line for that seating position, in the case of a fixed rigid routing device, measured horizontally and in a vertical longitudinal plane, the part of that anchorage that attaches to a tether hook may, at the manufacturer's option (with said option selected prior to, or at the time of, certification of the vehicle) be located outside that zone.

(c) The measurement of the location of the flexible or deployable routing device described in S6.2.1.2(b)(1) is made with SFAD 2 properly attached to the lower anchorages. A 40 mm wide nylon tether strap is routed through the routing device and attached to the tether anchorage in accordance with the written instructions required by S12 of this standard. The forwardmost contact point between the strap and the routing device must be within the stated limit when the tether strap is flat against the top surface of the SFAD and tensioned to 55 to 65 N. In seating positions without lower anchorages of a child restraint anchorage system, the SFAD 2 is held with its central lateral plane in the central vertical longitudinal plane of the seating position. The adjustable anchor attaching bars of the SFAD 2 are replaced by spacers that end flush with the back surface of the SFAD.

S6.2.2 Subject to S6.2.2.2, the part of each tether anchorage to which a tether hook attaches must be located within the shaded zone shown in figures 3 through 7 to this section of the designated seating position for which it is installed. The zone is defined with reference to the seating reference point (*see* § 571.3). (For purposes of the figures, ''H Point'' means seating reference point.) A tether anchorage may be recessed in the seat back, provided that it is not in the strap wrap-around area at the top of the vehicle seat back. For the area under the vehicle seat, the forwardmost edge of the shaded zone is defined by a vertical plane 120 mm rearward of the ''H Point,'' as shown in figure 3 to this section.

S6.2.2.1 Subject to S6.2.2.2, for vehicles with adjustable or removable head restraints or no head restraints, the tether anchorage to which a tether hook attaches must be located outside the zone created by a 325 mm radius sphere with its center on the R-point and truncated horizontally at 230 mm below the sphere's center as shown in figures 8 and 9 to this section.

S6.2.2.2 In the case of a vehicle that—

(a) Has a user-ready tether anchorage for which no part of the shaded zone shown in figures 4 through 7 and 10 to this section of the designated seating position for which the anchorage is installed is accessible without the need for folding the seatback (other than the head restraint) or removing a seating component of the vehicle; and

(b) Has a tether strap routing device that is—

(1) Not less than 65 mm behind the torso line for that seating position, in the case of a flexible routing device or a deployable routing device, measured horizontally and in a vertical longitudinal plane; or

(2) Not less than 100 mm behind the torso line for that seating position, in the case of a fixed rigid routing device, measured horizontally and in a vertical longitudinal plane, the part of that anchorage that attaches to a tether hook may, at the manufacturer's option (with said option selected prior to, or at the time of, certification of the vehicle) be located outside that zone.

(c) The measurement of the location of the flexible or deployable routing device described in S6.2.2.2(b)(1) is made with SFAD 2 properly attached to the lower anchorages. A 40 mm wide nylon tether strap is routed through the routing device and attached to the tether anchorage in accordance with the written instructions required by S12 of this standard. The forwardmost contact point between the strap and the routing device must be within the stated limit when the tether strap is flat against the top surface of the SFAD and tensioned to 55 to 65 N. In seating positions without lower anchorages of a child restraint anchorage system, the SFAD 2 is held with its central lateral plane in the central vertical longitudinal plane of the seating position. The adjustable anchorage attaching bars of the SFAD 2 are replaced by spacers that end flush with the back surface of the SFAD 2.

S6.3 *Strength requirements for tether anchorages.* (a) When tested in accordance with S8, the tether anchorage must not separate completely from the vehicle seat or seat anchorage or the structure of the vehicle.

(b) Provisions for simultaneous and sequential testing:

(1) In the case of vehicle seat assemblies equipped with more than one tether anchorage, the force referred to in this S6.3 may, at the agency's option, be applied simultaneously to each of those tether anchorages. However, that force may not be applied simultaneously to tether anchorages for any two adjacent seating positions whose midpoints are less than 400 mm apart, as measured in accordance with S6.3(b)(i) and (ii) and figure 20 to this section.

(i) The midpoint of the seating position lies in the vertical longitudinal plane that is equidistant from vertical longitudinal planes through the geometric center of each of the two lower anchorages at the seating position. For those seating positions that do not provide lower anchorages, the midpoint of the seating position lies in the vertical longitudinal plane that passes through the SgRP of the seating position.

(ii) Measure the distance between the vertical longitudinal planes passing through the midpoints of the adjacent seating positions, as measured along a line perpendicular to the planes.

(2) A tether anchorage of a particular child restraint anchorage system will not be tested with the lower anchorages of that anchorage system if one or both of those lower anchorages have been previously tested under this standard.

S6.4 *Marking and conspicuity requirements for tether anchorages.* Vehicles subject to Standard No. 225 (this section) shall meet S6.4 according to the phase-in schedule specified in S13 of this standard.

(a) For each tether anchorage installed pursuant to S4 of this standard, there shall be a permanent marking that:

(1) Consists of one of the pictograms shown in figure 25 to this section that is not less than 20 mm in height;

(2) Except for vehicles that use a routing device per S6.2.2.2, the center of the pictogram in the longitudinal direction must be in the vertical longitudinal plane that passes through the center of the tether anchorage bar (± half of the tether anchorage length), as shown in figure 26 (Left) to this section;

or the center of the pictogram in the lateral direction must be in the horizontal lateral plane that passes through the center of the tether anchorage bar (± half of the pictogram height), as shown in figure 26 (right) to this section.

(3) The nearest edge of the marking shall be located not more than 100 mm away from the tether anchorage bar as shown in figure 27 to this section. No other attachment feature to secure occupant items (*i.e.,* cargo hooks or similar) shall be nearer to the marking than the distance from the marking to the tether anchorage. Vehicles with routing devices per S6.2.2.2 may use tags attached to the routing device.

(b) The tether anchorage bar may be covered by a cap or cover that is removable without the use of any tool, provided that the cap or cover is permanently labeled with a marking meeting the requirements of S6.4(a)(1). If the cap or cover is permanently attached to the vehicle, the tether anchorage is not required to be separately marked. If the cap or cover is not permanently attached to the vehicle, the tether anchorage must also be marked with the symbol meeting S6.4(a)(1) through (3).

(c) For vehicles that have a cargo cover that needs to be moved or removed to access the tether anchorages, the cargo cover must be permanently marked with the symbol meeting S6.4.1(a)(1) of this standard for each tether anchorage that is accessible under the cargo cover. Tether anchorages under the cargo cover must also be marked per S6.4(a).

* * * * *

S8 *Test procedures.* Each vehicle shall meet the requirements of S6.3 when tested according to the following procedures. * * *

S8.1 Apply the force specified in S6.3 as follows—

* * * * *

S9. *Requirements for the lower anchorages of the child restraint anchorage system.* Vehicles subject to Standard No. 225 (this section) shall meet the lower anchorage requirements specified in S9.2 and S9.5 according to the phase-in schedule specified in S13 of this standard.

S9.1 *Configuration of the lower anchorages*

S9.1.1 * * *

(d) The bars must not be capable of being stowable or foldable.

* * * * *

S9.2 *Location of the lower anchorages.*

* * * * *

S9.2.4 The lower anchorages shall be located such that the lower anchorage depth tool depicted in Drawing Package, *Anchorage Depth Tool,* dated April 2020 (incorporated by reference; *see* § 571.5), measures an anchorage depth of 25 mm or less using the procedure in S11(c) of this standard.

S9.2.5 The lower anchorages shall be located such that the tool depicted in Drawing Package, *Clearance Angle Tool,* dated April 2020 (incorporated by reference; *see* § 571.5), measures a clearance angle of at least 54 degrees using the procedure in S11(b) of this standard.

* * * * *

S9.5 *Marking and conspicuity requirements.*

S9.5.1 *Requirements for lower anchors.* Lower anchorages must meet the requirements in S9.5.1(a) or (b).

(a) For each bar installed pursuant to S4, the vehicle shall be permanently marked with a circle:

(1) That is not less than 13 mm in diameter;

(2) That is either solid or open, with or without words, symbols, or pictograms, provided that if words, symbols or pictograms are used, their meaning is explained to the consumer in writing, such as in the vehicle's owner's manual; and

(3) That is located such that its center is on each seat back between 50 and 100 mm above or on the seat cushion 100 ±25 mm forward of the intersection of the vertical transverse and horizontal longitudinal planes intersecting at the horizontal centerline of each lower anchorage, as illustrated in figure 22 to this section. The center of the circle must be in the vertical longitudinal plane that passes through the center of the bar (±25 mm).

(4) The circle may be on a tag.

(b) The vehicle shall be configured such that the following is visible: Each of the bars installed pursuant to S4, or a permanently attached guide device for each bar. The bar or guide device must be visible without the compression of the seat cushion or seat back, when the bar or device is viewed, in a vertical longitudinal plane passing through the center of the bar or guide device, along a line making an upward 30-degree angle with a horizontal plane. Seat backs are in the nominal design riding position. The bars may be covered by a removable cap or cover, provided that the cap or cover is permanently marked with words, symbols or pictograms whose meaning is explained to the consumer in written form as part of the owner's manual.

S9.5.2 *Requirements for lower anchors.* Lower anchorages must meet the requirements in S9.5.2(a) and (b), as applicable.

(a) For each bar installed pursuant to S4, the vehicle shall be permanently marked with a symbol that:

(1) Is not less than 13 mm in diameter;

(2) Contains the pictogram shown in figure 24 to this section; and

(3) Is located such that its center is on each seat back between 50 and 100 mm above or on the seat cushion between 100 to −50 mm forward of the intersection of the vertical transverse and horizontal longitudinal planes intersecting at the horizontal centerline of each lower anchorage, as illustrated in figure 19 to this section. The center of the symbol must be in the vertical longitudinal plane that passes through the center of the bar (±25 mm).

(4) The symbol may be on a tag.

(b) The bars may be covered by a removable cap or cover, provided that the cap or cover is permanently marked with the pictogram shown in figure 24 to this section. If the cap or cover is permanently attached to the vehicle, the lower anchorage bars are not required to be separately marked with the pictogram. If the cap or cover is not permanently attached to the vehicle, the lower anchorage bars must also be marked with the symbol meeting S9.5.2(a)(1) through (4).

* * * * *

S11. *Test procedures.* Each vehicle shall meet the requirements of this standard when tested according to the following procedures. Where a range of values is specified, the vehicle shall be able to meet the requirements at all points within the range.

(a) *Strength requirements*—(1) *Forward force direction.* Place SFAD 2 in the vehicle seating position and attach it to the two lower anchorages of the child restraint anchorage system. Do not attach the tether anchorage. A rearward horizontal force of 135 ±15 N is applied to the center of the lower front crossbar of SFAD 2 to press the device against the seat back as the fore-aft position of the rearward extensions of the SFAD is adjusted to remove any slack or tension. Apply a preload force of 500 N horizontally and in the vertical centerline of the SFAD 2 at point X. Increase the pull force as linearly as practicable to a full force application of 11,000 N in not less than 24 seconds and not more than 30 seconds and maintain at an 11,000 N level for 1 second.

(2) *Lateral force direction.* Place SFAD 2 in the vehicle seating position and attach it to the two lower anchorages of the child restraint anchorage system. Do not attach the tether anchorage. A

rearward force of 135 ±15 N is applied to the center of the lower front crossbar of SFAD 2 to press the device against the seat back as the fore-aft position of the rearward extensions of the SFAD is adjusted to remove any slack or tension. Apply a preload force of 500 N horizontal and perpendicular to the longitudinal centerline of the SFAD 2 at point X of the test device. Increase the pull force as linearly as practicable to a full force application of 5,000 N in not less than 24 seconds and not more than 30 seconds and maintain at a 5,000 N level for 1 second.

(b) *Clearance angle.* The seat back angle, if adjustable, is set at the manufacturer's nominal design seat back angle. If the position is not specified, set the seat back at the first detent rearward of 25° from the vertical. Remove or open any lower anchorage cover, if present, to expose the lower anchorage. To measure clearance angle, attach the clearance angle tool to the lower anchorage and apply a vertical force of 67 N (15 lbf) to the tool. Measure the angle (with respect to the horizontal) of the tool while the force is being applied.

(c) *Anchorage depth.* The seat back angle, if adjustable, is set at the manufacturer's nominal design seat back angle. If the position is not specified, set the seat back at the first detent rearward of 25° from the vertical. To measure the anchorage depth, subtract 30 degrees from the measured seat pan angle to calculate the view angle. With the anchorage depth tool (*see* figure 28 to this section) on a flat surface, adjust the view bar to read the view angle. Slide the zeroing strip along the view bar so that it is barely touching the top of the depth tool hook. Move the view bar forward, so the end of the zeroing strip is aligned with the zero-scribe line. For hidden anchorages, slide the anchorage depth tool so that it reads 0 mm at the rear edge of the slider. For visible anchorages, align the depth gauge to 25 mm so that negative values can be read. Attach the depth tool centered to the lower anchorage. Adjust the depth tool base to be within ±2 degrees of the view angle (30 degrees minus seat pan angle) to set the tool-parallel to the seat pan angle. Move the entire slider bar forward until the zeroing strip contacts the vehicle seat back or any other vehicle part.

S12. *Written instructions.* Vehicles subject to Standard No. 225 (this section) shall meet the written instruction requirements specified in either S12.1 or S12.2 according to the phase-in schedule specified in S13.

S12.1 Written instructions shall:

(a) Indicate which seating positions in the vehicle are equipped with tether anchorages and child restraint anchorage systems;

(b) In the case of vehicles required to be marked as specified in paragraphs S4.1 and S9.5 of this standard, explain the meaning of markings provided to locate the lower anchorages of child restraint anchorage systems; and

(c) Include instructions that provide a step-by-step procedure, including diagrams, for properly attaching a child restraint system's tether strap to the tether anchorages.

S12.2 Written instructions shall:

(a) Indicate which seating positions in the vehicle are equipped with tether anchorages and child restraint anchorage systems;

(b) In the case of vehicles required to be marked as specified in paragraphs S4.1 and S9.5 of this standard, explain the meaning of markings provided to locate the lower anchorages of child restraint anchorage systems and the top tether anchorages;

(c) Include instructions that provide a step-by-step procedure, including diagrams, for properly attaching a child restraint system's tether strap to the tether anchorages;

(d) Include instructions on how to locate and access the tether anchorage and the lower anchorages; and

(e) Use the following terms when referring to the different components of the child restraint anchorage system that are used to connect the child restraint system to the vehicle: ''lower anchor'' means the lower anchorage of the child restraint anchorage system in the vehicle, ''tether anchor'' means the top tether anchorage of the child restraint anchorage system in the vehicle, ''lower anchor attachment'' means the child restraint system or the detachable base's (in the case of a rear-facing child restraint with a detachable base) lower anchorage connector and the lower anchorage strap (for flexible lower anchorage attachments), ''rigid lower anchor attachment'' means the child restraint system or the detachable base's (in the case of a rear-facing child restraint with a detachable base) lower anchorage connector that is rigidly attached to the CRS or detachable base, respectively, and does not have a lower anchorage strap, and ''tether'' means the child restraints system's tether hook and tether strap.

S13 *Phase-in schedule.* The S13 phase in schedule details when listed requirements become inactive and are replaced by newer requirements. Requirements in Standard No. 225 (this section) not listed in S13 shall be in effect before, during, and after the S13 phase-in.

S13.1 *Vehicle certification information.* At any time during the production years ending August 31, 2029, and August 31, 2030, each manufacturer shall, upon request from the Office of Vehicle Safety Compliance, provide information identifying the vehicles (by make, model and vehicle identification number) that have been certified as complying with the child restraint anchorage usability requirements of this standard. Manufacturers shall specify the number of vehicles meeting each phase-in percentage. The manufacturer's designation of a vehicle as a certified vehicle is irrevocable.

S13.1.1 *Pre phase-in.* Vehicles manufactured before September 1, 2028, are subject to S6.1.1, S6.2.1, S9.2.1, S9.2.2, S9.2.3, S9.5.1, and S12.1 of this standard.

S13.1.2 *Phase-in year 1.* Vehicles manufactured on or after September 1, 2028, and before September 1, 2029. The total number of individual vehicles complying with S6.1.2, S6.2.2, S6.4, S9.2 (except for S9.2.2(a)), S9.5.2, and S12.2 of this standard shall be not less than 20 percent of a vehicle manufacturer's total production for this time period. The remaining 80 percent of a vehicle manufacturer's total production are subject to S6.1.1, S6.2.1, S9.2.1, S9.2.2, S9.2.3, S9.5.1, and S12.1 of this standard.

S13.1.3 *Phase-in year 2.* Vehicles manufactured on or after September 1, 2029, and before September 1, 2030. The total number of individual vehicles complying with S6.1.2, S6.2.2, S6.4, S9.2 (except for S9.2.2(a)), S9.5.2, and S12.2 of this standard shall be not less than 50 percent of a vehicle manufacturer's total production for this time period. The remaining 50 percent of a vehicle manufacturer's total production are subject to S6.1.1, S6.2.1, S9.2.1, S9.2.2, S9.2.3, S9.5.1, and S12.1 of this standard.

S13.1.4 *Phase-in year 3 and beyond.* Vehicles manufactured on or after September 1, 2030. The total number of vehicles complying with S6.1.2, S6.2.2, S6.4, S9.2 (except for S9.2.2(a)), S9.5.2, and S12.2 shall be not less than 100 percent of a vehicle manufacturer's total production.

S13.2 *Vehicles produced by more than one manufacturer.*

S13.2.1 For the purpose of calculating average annual production of vehicles for each manufacturer and the number of vehicles manufactured by each manufacturer under S13.1.1 through S13.1.4, a vehicle produced by more than one manufacturer shall be

attributed to a single manufacturer as follows:

(a) A vehicle which is imported shall be attributed to the importer.

(b) A vehicle manufactured in the United States by more than one manufacturer, one of which also markets the vehicle, shall be attributed to the manufacturer which markets the vehicle.

S13.2.2 A vehicle produced by more than one manufacturer shall be attributed to any one of the vehicle's manufacturers specified by an express written contract, reported to the National Highway Traffic Safety Administration under 49 CFR part 585, between the manufacturers so specified and the manufacturer to which the vehicle would otherwise be attributed under S13.2.1.

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Figures to § 571.225

* * * * *

Figure 8 to § 571.225. Side View of 325 mm Radius Sphere Zone From R-Point, Truncated at 230 mm Below the Center

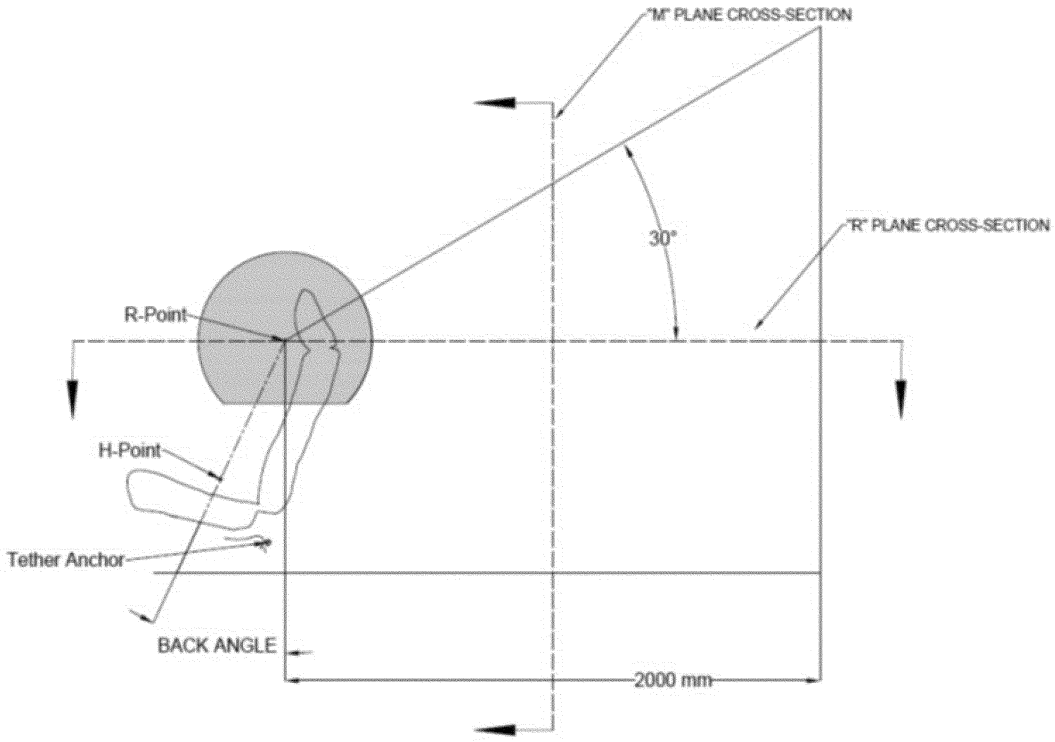


Figure 9 to § 571.225. Three-Dimensional 325 mm Radius Sphere Zone From R-Point, Truncated Along the Lower Edge at 230 mm Below Its Center

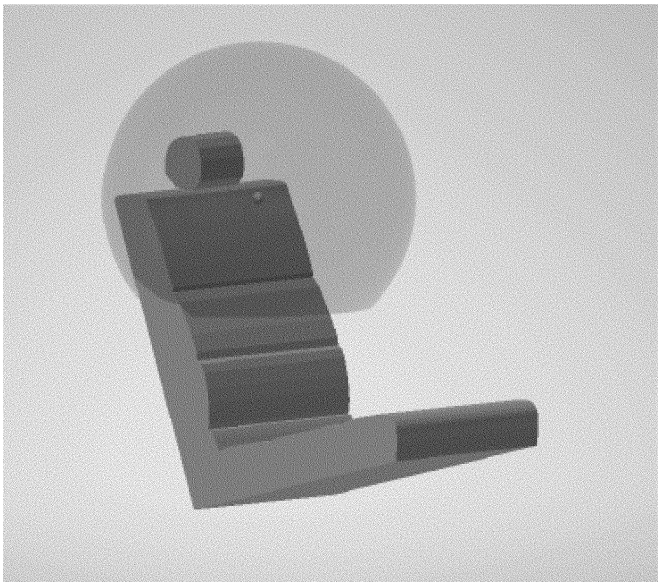
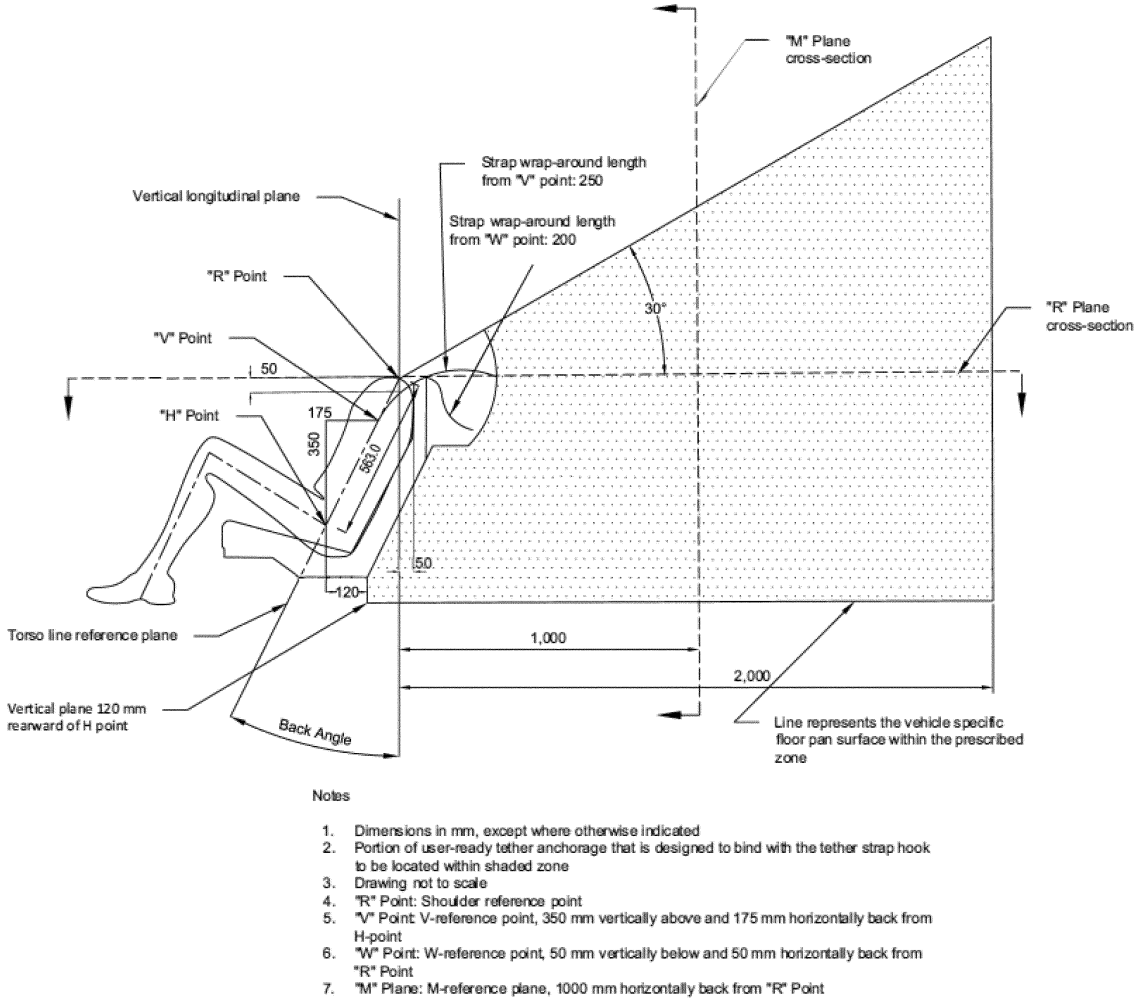


Figure 10 to § 571.225—Side View. User Ready Tether Anchorage Location



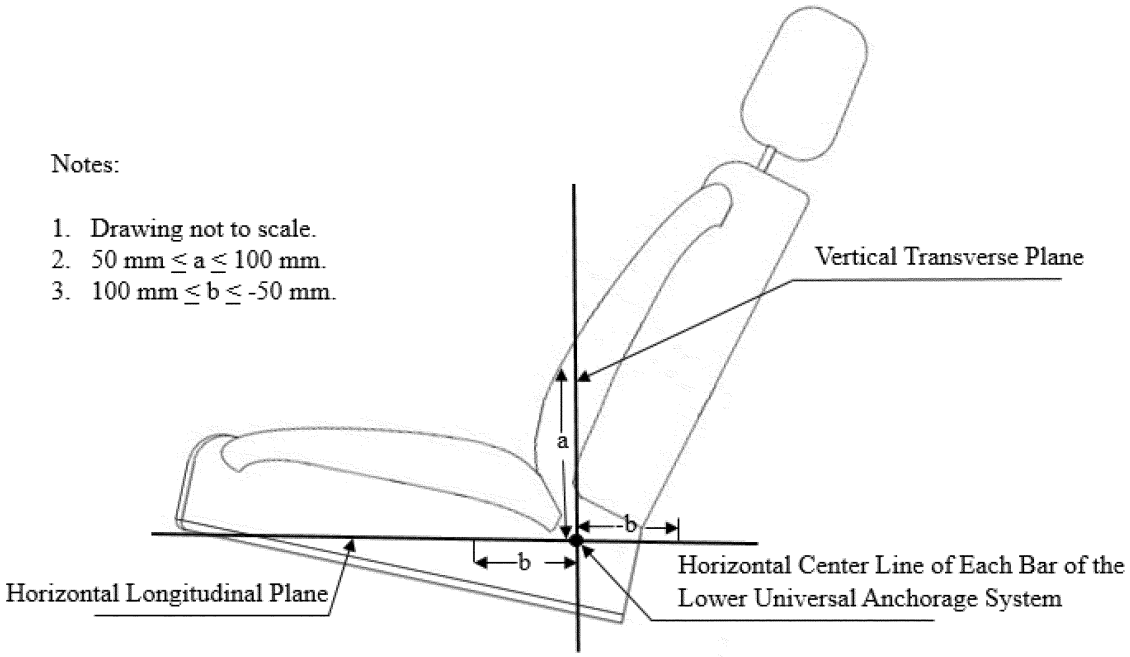
Notes

1. Dimensions in mm, except where otherwise indicated
2. Portion of user-ready tether anchorage that is designed to bind with the tether strap hook to be located within shaded zone
3. Drawing not to scale
4. "R" Point: Shoulder reference point
5. "V" Point: V-reference point, 350 mm vertically above and 175 mm horizontally back from H-point
6. "W" Point: W-reference point, 50 mm vertically below and 50 mm horizontally back from "R" Point
7. "M" Plane: M-reference plane, 1000 mm horizontally back from "R" Point

Figure 11 to § 571.225. [Reserved]

* * * * *

Figure 19 to § 571.225. Placement of Symbol on the Seat Back and Seat Cushion of Vehicle



* * * * *

Figure 23 to § 571.225. Clearance Angle Tool

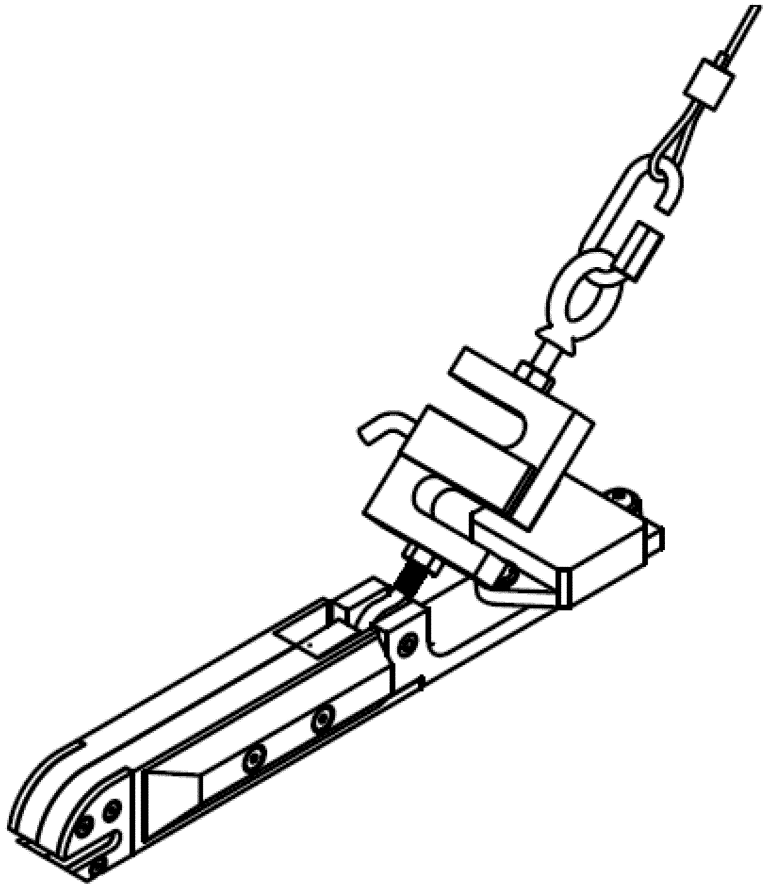


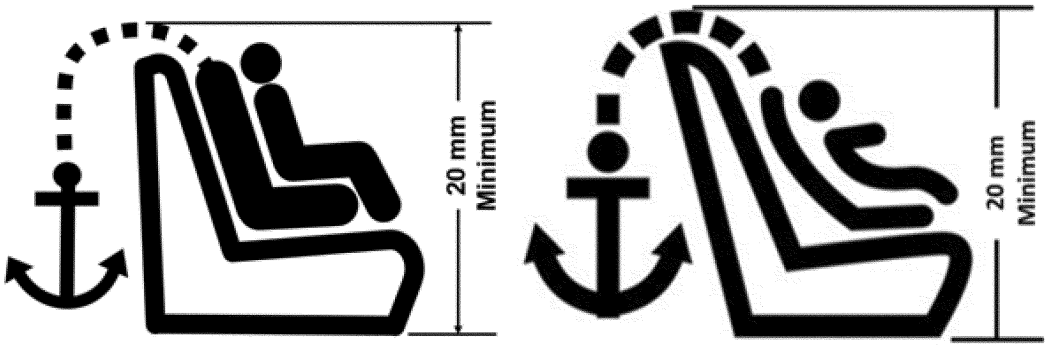
Figure 24 to § 571.225—Lower Anchorage Symbol

Figure 25 to § 571.225. Tether Anchorage Symbols

Note 1 to Figure 24 to § 571.225: Drawing not to scale.

Note 2 to Figure 24 to § 71.225: Symbol may be shown in mirror image.

Note 3 to Figure 24 to § 571.225: Color of the symbol at the option of the manufacturer.

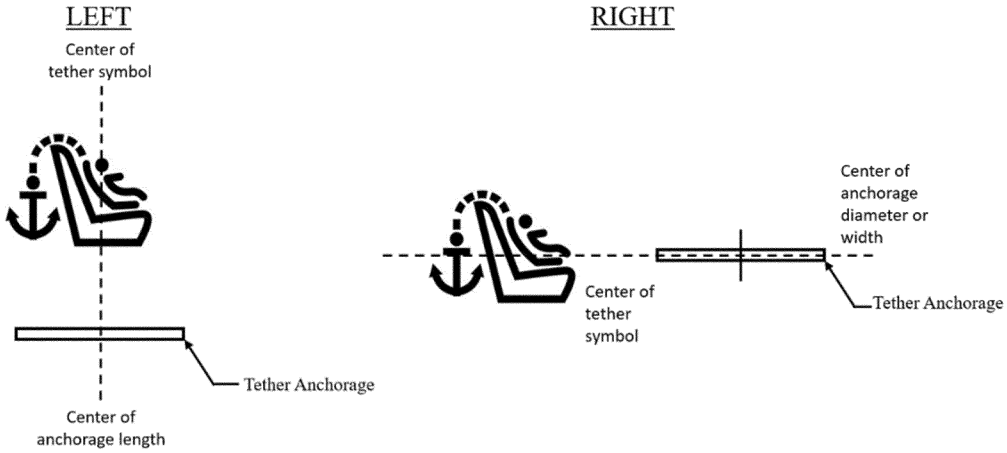


Note 1 to Figure 25 to § 571.225: Drawing not to scale.

Note 2 to Figure 25 to § 571.225: Symbol may be shown in mirror image.

Note 3 to Figure 25 to § 571.225: Color of the symbol at the option of the manufacturer.

Figure 26 to § 571.225. Tether Anchorage Marking Location—Alignment (No Cover)



Note 1 to Figure 26 to § 571.225: (Tolerance of ± half of the anchorage length)/(Tolerance of ± half of the pictogram height).

Figure 27 to § 571.225. Tether Anchorage Marking Location—Distance (No Cover)

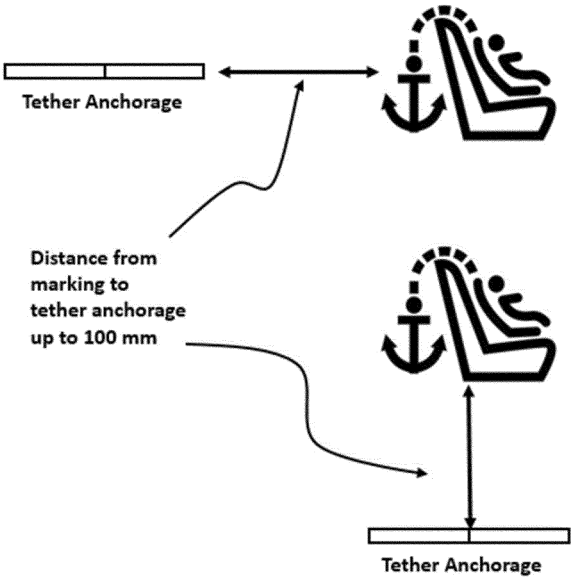
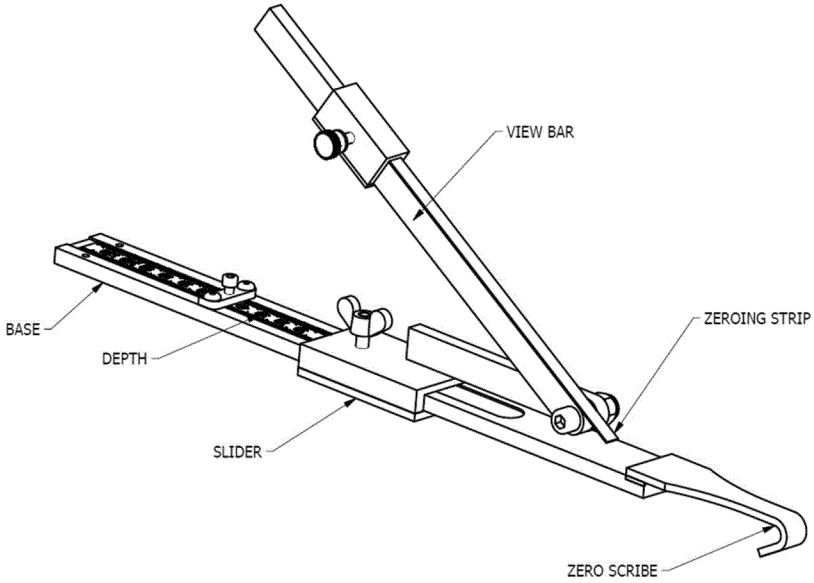


Figure 28 to § 571.225. Anchorage Depth Tool



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PART 585—PHASE-IN REPORTING REQUIREMENTS

■ 5. The authority citation for part 585 continues to read as follows:

Authority: 49 U.S.C. 322, 30111, 30115, 30117, and 30166; delegation of authority at 49 CFR 1.95.

■ 6. Add subpart O to read as follows:

Subpart O—Child Restraint Anchorage Systems Phase-In Reporting Requirements

Sec.

585.135 Scope.
585.136 Purpose.
585.137 Applicability.
585.138 Definitions.
585.139 Response to inquiries.
585.140 Reporting requirements.
585.141 Records.

Subpart O—Child Restraint Anchorage Systems Phase-In Reporting Requirements

§ 585.135 Scope.

This subpart establishes requirements for manufacturers of passenger cars, and of trucks and multipurpose passenger vehicles with a gross vehicle weight rating (GVWR) of 3,855 kilograms (8,500 pounds) or less, and of buses with a GVWR of 4,536 kg (10,000 lb) or less, to submit a report per § 585.140, and maintain records related to the report according to § 585.141, concerning the number of such vehicles that meet the requirements of Standard No. 225, *Child restraint anchorage systems* (49 CFR 571.225).

§ 585.136 Purpose.

The purpose of these reporting requirements is to assist the National Highway Traffic Safety Administration in determining whether a manufacturer has complied with Standard No. 225 (49 CFR 571.225).

§ 585.137 Applicability.

This subpart applies to manufacturers of passenger cars, and of trucks and multipurpose passenger vehicles with a gross vehicle weight rating (GVWR) of 3,855 kilograms (8,500 pounds) or less, and of buses with a GVWR of 4536 kg (10,000 lb) or less, for which Standard No. 225 (49 CFR 571.225) applies. However, this subpart does not apply to vehicles excluded by S5 of Standard No. 225 from the requirements of that standard.

§ 585.138 Definitions.

(a) All terms defined in 49 U.S.C. 30102 are used in their statutory meaning.

(b) Bus, gross vehicle weight rating or GVWR, multipurpose passenger vehicle, passenger car, and truck are used as defined in 49 CFR 571.3.

(c) *Production year* means the 12-month period between September 1 of one year and August 31 of the following year, inclusive.

§ 585.139 Response to inquiries.

At any time during the production years ending August 31, 2029, and August 31, 2030, each manufacturer shall, upon request from the Office of Vehicle Safety Compliance, provide information identifying the vehicles (by make, model and vehicle identification number) that have been certified as complying with Standard No. 225 (49 CFR 571.225). The manufacturer's designation of a vehicle as a certified vehicle is irrevocable.

§ 585.140 Reporting requirements.

(a) *General reporting requirements.* Within 60 days after the end of the production years ending August 31, 2029, and August 31, 2030, each manufacturer shall submit a report to the National Highway Traffic Safety Administration concerning its compliance with the child restraint anchorage system requirements of Standard No. 225 (49 CFR 571.225) for applicable vehicles produced in that year. Each report shall:

(1) Identify the manufacturer;

(2) State the full name, title, and address of the official responsible for preparing the report;

(3) Identify the production year being reported on;

(4) Contain a statement regarding whether or not the manufacturer complied with the child restraint anchorage system requirements of Standard No. 225 (49 CFR 571.225) for the period covered by the report and the basis for that statement;

(5) Provide the information specified in paragraph (b) of this section;

(6) Be written in the English language; and

(7) Be submitted to: Administrator, National Highway Traffic Safety Administration, 1200 New Jersey Ave. SE, West Building, Washington, DC 20590.

(b) *Report content*—(1) *Basis for phase-in production goals.* Each manufacturer must provide the number of passenger cars and trucks and multipurpose passenger vehicles with a gross vehicle weight rating (GVWR) of 3,855 kilograms (8,500 pounds) or less, and buses with a GVWR of 4,536 kg (10,000 lb) or less manufactured for sale in the United States for each of the most recent three previous production years, or, at the manufacturer's option, for the most recently ended production year. A new manufacturer that has not previously manufactured these vehicles for sale in the United States must submit a report at the end of the initial production year for the number of such vehicles manufactured during the initial production year.

(2) *Production.* Each manufacturer must report for the production year for which the report is filed: the number of passenger cars and trucks and multipurpose passenger vehicles with a gross vehicle weight rating (GVWR) of 3,855 kilograms (8,500 pounds) or less, and buses with a GVWR of 4,536 kg (10,000 lb) or less, that do and do not meet S13 of Standard No. 225 (49 CFR 571.225).

(3) *Vehicles produced by more than one manufacturer.* Each manufacturer whose reporting of information is affected by one or more of the express written contracts permitted by S13.2.1(c) of Standard No. 225 (49 CFR 571.225) must:

(i) Report the existence of each contract, including the names of all parties to the contract, and explain how the contract affects the report being submitted.

(ii) Report the actual number of vehicles covered by each contract.

§ 585.141 Records.

Each manufacturer must maintain records of the Vehicle Identification Number for each vehicle for which information is reported under § 585.140 until December 31, 2032.

Issued in Washington, DC, under authority delegated in 49 CFR 1.95 and 501.

Adam Raviv,

Chief Counsel.

[FR Doc. 2024–31142 Filed 1–6–25; 8:45 am]

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